(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 September 2006 (21.09.2006)

PCT

(10) International Publication Number
WO 2006/097111 A2

(51) International Patent Classification:
A61M 5/158 (2006.01) *A61M 39/02* (2006.01)
A61M 25/06 (2006.01)

(21) International Application Number:
PCT/DK2006/050005

(22) International Filing Date:
23 February 2006 (23.02.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/662,667 17 March 2005 (17.03.2005) US
PA200500389 17 March 2005 (17.03.2005) DK

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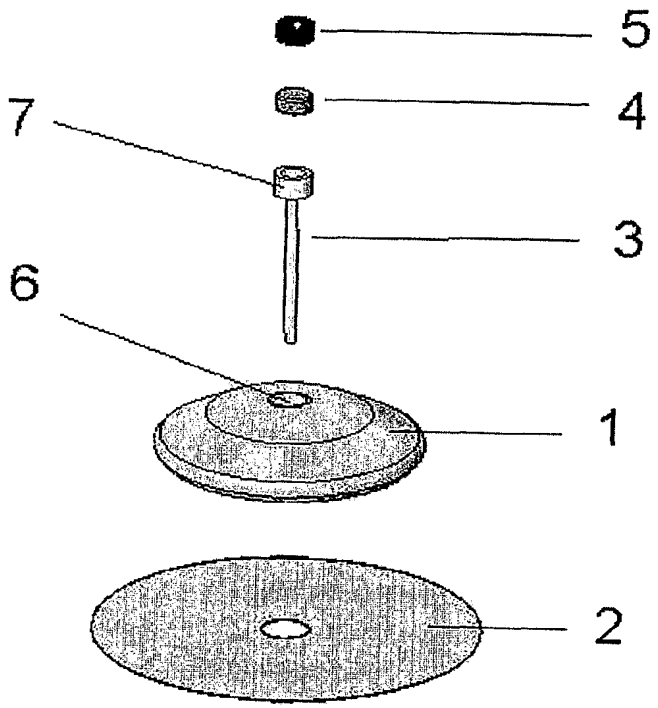
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: GATEWAY SYSTEM



(57) Abstract: This invention relates to an injection site or gateway or a system comprising such an injection site or gateway. The gateway is placed subcutaneously in the user can replace repeated injections by syringes or injection pens which will reduce trauma to the patients' skin and at the same time keep the injection place free of infections. In one form the invention concerns a system comprising an inserter device and a gateway for subcutaneous injection of fluid where comprises a distal surface (1a) corresponding to a proximal surface (1b) integrated with the inserter device. In another form the invention concerns a gateway for subcutaneous injection of fluid, which gateway comprises - a body (1) with at least one through-going opening (6) with an entrance and an outlet, and at least one cannula (3) placed in fluid connection with the through-going opening (6) and having a proximal end protruding from the lower side of the body (1); - and at the entrance of the through-going opening (6) medication can be injected by a delivery device (20) which delivery device (20) has protruding parts (22) covering the entrance when delivering medication to the gateway and which protruding parts (22) form an inner opening with a diameter di; wherein the surface of the entrance is shaped in such a way that the cross- section of the top part of entrance, i.e. from the top of the entrance to a position di/3 below the top, do not exceed di.

WO 2006/097111 A2

Gateway system

Background of the invention

This invention relates to an injection site or gateway or a system comprising such an injection site or gateway. The gateway is placed subcutaneously in the user can replace repeated injections by syringes or injection pens which will reduce trauma to the patients' skin and at the same time keep the injection place free of infections.

Gateways as such are already known. In previous documents the use of a needle assembly comprising a gateway and a pen-type injector is disclosed by this assembly it is possible to provide subcutaneous or intravenous injections using a blunt tipped needle. It is not indicated in the documents how the gateway is inserted. It would not be possible to use even a relatively short, sharp needle for injection in this gateway as the risk of penetrating the side of the soft cannula with a hypodermic needle would be considerable, as the steering or piloting of the needle when penetrating the septum is small and at the same time the hard case housing is very short.

Also other types of gateways are known, e.g. gateways comprising an elongated housing having an internal passageway extending from one end of the housing to the opposite end in the longitudinal sense. A cannula tube is connected to the housing and extends from the distal end of the passageway. The cannula tube is connected to the housing by means of a bushing and immediately adjacent to the proximal end of the cannula is a self-sealing silicon membrane. The membrane is in the form of a plug engaging the rear end of the bushing. In this way there is only a minimum of dead space i.e. internal volume in the passageway of the housing. This gateway has a rather long hard case housing which reduces the risk of penetrating the cannula with a sharp needle, but the gateway is also intended to be inserted manually in a very low angle. After insertion the gateway is

placed almost parallel to the patients' skin and this parallel position can make it difficult for the patients themselves to inject medical substances through the gateway.

It is an aim of the present invention to provide a gateway which is easy for the patient to place and to use for self-administration of drugs or other medicaments. Also it is an aim that the gateway after placement onto the patients' skin is noticed as little as possible by the patient when the patient is not actually injecting medication.

Summary of the invention

According to the present invention an injection prepared gateway for subcutaneous injection of fluid, which gateway comprises: a body with a through-going opening; a mounting pad attached unreleasably to the body and having an adhesive surface; at least one cannula and at least one penetrating member having a proximal end protruding from the lower side of the body; a septum placed at the distal end of the cannula in the through-going opening; where the septum restricts the access to the cannula, so access to the cannula can be reached by a drug delivery device being able to penetrate the septum. The gateway is releasably connected to a biasing unit in an inserter part which part can bring the gateway from a retracted to a forward position when released.

Preparing the gateway for injection by placing it in an injector assures that a non-skilled user can perform a correct subcutaneously placement of the gateway under sterile conditions. A correct placement of the gateway is essential for a completely user controlled operation of medication. Preferably the injector is of a single use type as for example known from WO 03/026728 (inset™). After injection the gateway is secured to the patient by the mounting pad and due to a smooth surface and low height of the body of the gateway it is unlikely that the gateway get caught in anything. That the gateway has a smooth surface means that the surface all the way around the body especially at the edge close to the mounting pad is without protrusions, openings and pointing corners. The desire to keep the surface smooth can

generally cause a problem when the unit has to be fastened firmly inside an inserter during insertion but this problem has been solved according to the present invention.

The word "cannula" is used for a hollow member protruding from the body of the gateway; the cannula is inserted into the patient and leads the fluid drug from the inside of the gateway and into the body of the patient. A cannula can function as penetrating member if it is made of a hard material such as metal or a hard plastic, and in this case the cannula and the penetrating member are one and the same. Preferably the cannula of the injection prepared gateway is made of a soft material as the soft cannula is more compatible with the skin tissue than a hard cannula. In this case it will be necessary to have a separate penetrating member such as a pointy needle which can cut an opening in the patients' skin and prepare the entering of the cannula, after insertion of the soft cannula the penetrating member will be removed while leaving the cannula in the patients skin as a pass way for the drugs to be delivered. Also it is preferred that the penetrating member in the form of an insertion needle is fastened unreleasably to the inserter device and extending inside and beyond the cannula, in this situation the insertion needle will be removed together with the inserter device and the user will not have to remove a separate needle or needle unit after having removed the inserter device.

In one embodiment of the invention more than one cannula and/or penetrating members are protruding from the lower side of the body of the gateway.

This could be the case if the single penetrating member was replaced with a group of shorter penetrating members only protruding a few millimeters and being supplied with medication from a common chamber inside the body of the gateway.

It could also be the case if the gateway was to be used together with a metering unit for e.g. glucoses in the blood. When used as a continuous metering device with the possibility of simultaneous administration of

medication, the patient will need to have a probe inserted which could provide the metering device with access to the blood. The probe can be inserted together with the cannula through which the medication is injected or it can be inserted at another position by another penetrating member. In a preferred embodiment the gateway can perform as a base for a metering device such as the device Navigator™ sold by Abbotts Diabetes Care.

Preferably the injection prepared gateway is provided with a steering part which will make it easier for a user to perform injections through the gateway once the gateway has been inserted. This will be a significant advantage for patients with bad eyesight or in situations where the gateway is placed at positions on the patients' body where it is difficult for the patient to see the entrance of the injection needle.

According to the present invention the steering part can both be placed inside the through-going opening and on the distal surface of the body of the gateway.

If the steering part is placed on the distal surface, the steering part can have the form of tracks, which tracks can be both protruding and/or recessing from the surface. Preferably the tracks form an opposite impression of a part of the inserter device, preferably formed as the injection end of an injection pen.

In a preferred embodiment the tracks are formed as one or more recesses, preferably of a circular form which will allow for the injection pen to have prolonged sides covering the needle when the injection pen is not used for injection, and protecting the user against needle sticks.

In a preferred embodiment the releasable part of the steering part forms a unique interface between the drug delivery device and the gateway and assures that it is only possible to use one given injector device. "Unique interface" means that the two surfaces facing each other i.e. the surface of the gateway and the surface of the drug delivery device correspond to each other like hand and glove. This is an advantage if for example a given injector device is used for a certain drug which will make it almost impossible for the

patient to inject a drug not prescribed to the patient. Also an interface which causes a very close fit between the drug delivery device and the gateway will ensure a minimum of dead space, that is internal volume inside the body of the gateway where an injected medicament stay unused. In another preferred embodiment at least a part of the steering part is releasably fastened to the body in order for the releasable part to act as an interchangeable adaptor between a drug delivery device and the gateway.

The injection prepared gateway can be fastened releasably to a slidable member inside the inserter part which slidable member is unreleasably fastened to the biasing unit.

The reason why it is preferred to fasten the injection prepared gateway to a slidable member which is not identical with the biasing unit is that it is simpler to connect the gateway to a unit which has the purpose of forming a connection between the biasing unit and the gateway than it is to connect the gateway directly to the biasing unit, as the biasing unit has a well defined purpose already which makes demands to the design of the biasing unit. The slidable member can be of a very simple construction as it is possible to adequately fastened the gateway to the slidably member simply by attaching the insertion needle unreleasably to the slidable member and inserting the insertion needle into the cannula of the gateway. The frictional resistance alone between the insertion needle and the cannula will then keep the gateway in the right position during insertion.

Preferable the proximal side of inserter part which is in contact with the body of the gateway is shaped to correspond closely to the gateway. That the inserter part is shaped to correspond to the gateway means that the end of the inserter part which is adjacent to the gateway closely follows the surface of the gateway and creates the largest possible contact between the slidable member and the gateway. This large contact assures that the gateway is steered more precisely through the inserter which results in a very precise – and therefore more painless – insertion.

Preferably the end of the inserter part which is adjacent to the gateway is shaped as the end of an injection pen and the surface of the gateway is formed with corresponding tracks. A lot of gateway users prefer to insert medication with injection pens as this is an easy way to perform insertion and assure correct dosage. Forming the surface of the slidable member adjacent to the gateway as an injection pen will have the result that formed tracks in the surface of the gateway will suit equally well to the slidable member and an injection pen.

In order to protect the injection prepared gateway when it is attached to the user, a cover corresponding to the gateway can be positioned on top of the body between the insertions performed by the user.

The injection prepared gateway is especially directed towards the use of insulin and by using the injection prepared gateway it is possible e.g. to replace the use of an insulin pump. An insulin pump provides the patient with a steady dosage of insulin through a soft tube connected to an infusion part fastened to the patient but the pump is an expensive unit and it is inconvenient for the patient to – at least periodically - carry the device and connecting tubing on the body.

The invention also concerns a system comprising an inserter device and a gateway for subcutaneous injection of fluid where the gateway comprises a body with at least one through-going opening, at least one cannula and a restriction for microorganisms placed at the distal end of the at least one cannula or in the at least one through-going opening; and which system comprises at least one penetrating member having a proximal end protruding from the lower side of the body; drugs to be injected is delivered to the gateway by a drug delivery device being able to pass the restriction for microorganisms, the gateway is releasably connected to a biasing unit in the inserter device which unit can bring the gateway from a retracted to a forward position when released, wherein the body of the gateway comprises a distal surface corresponding to a proximal surface integrated with the inserter device.

The word "integrated" means that the proximal surface can constitute a surface of the inside of the inserter or that the proximal surface can be constituted of a part releasably or unreleasably fastened to the inside of the inserter. In a preferred embodiment the proximal surface integrated with the delivery device belongs to a separate interface. In this application the words "interface" and "adaptor" is used interchangeably.

The invention also concerns a system comprising an inserter device, a gateway and an interface, where the gateway comprises a body with at least one through-going opening, at least one cannula and a restriction for microorganisms placed at the distal end of the at least one cannula or in the at least one through-going opening; and which system comprises at least one penetrating member having a proximal end protruding from the lower side of the body; drugs to be injected is delivered to the gateway by a drug delivery device being able to pass the restriction for microorganisms, the gateway is releasably connected to a biasing unit in the inserter device which unit can bring the gateway from a retracted to a forward position when released, wherein the interface provides a distal surface corresponding to the inserter and a proximal surface corresponding to the gateway.

The invention also concerns a system comprising a drug delivery device and a gateway for subcutaneous injection of fluid where the gateway comprises a body with at least one through-going opening, at least one cannula and a restriction for microorganisms placed at the distal end of the at least one cannula or in the at least one through-going opening; and which system comprises at least one penetrating member having a proximal end protruding from the lower side of the body; drugs to be injected is delivered to the gateway by the drug delivery device being able to pass the restriction for microorganisms, the gateway is releasably connected to a biasing unit in an inserter device which unit can bring the gateway from a retracted to a forward position when released, wherein the system also comprises a separate interface comprising a proximal surface corresponding to a distal surface of the gateway and a distal surface corresponding to a proximal surface of the delivery device.

The invention also concerns a system comprising an inserter device, a drug delivery device and a gateway for subcutaneous injection of fluid where the gateway comprises a body with at least one through-going opening, at least one cannula and a restriction for microorganisms placed at the distal end of the at least one cannula or in the at least one through-going opening; and which system comprises at least one penetrating member having a proximal end protruding from the lower side of the body; drugs to be injected is delivered to the gateway by the drug delivery device being able to pass the restriction for microorganisms, the gateway is releasably connected to a biasing unit in the inserter device, which unit can bring the gateway from a retracted to a forward position when released, wherein the gateway comprises a distal surface corresponding to a proximal surface integrated with the inserter device and to a proximal surface integrated with the delivery device. Preferably the gateway comprises a distal surface corresponding to a proximal surface of an interface and the interface has a distal surface corresponding to a proximal surface of the delivery device.

The advantage of these systems are that when using the whole system it is possible to combine standard units which are relatively non-expensive to produce with e.g. drug specific units which are more expensive but can assure that no mistakes are made e.g. when a user has to administer more than one medication to him/her self. Further self-administration of medication encourages individuals to participate in their own health care and provides structure for regular assessment and teaching about their drugs.

In a preferred embodiment the distal surface of the gateway comprises a steering part constituted of one or more parts inserted in the opening which part or parts are made of a relatively hard material for example metal or hard plastic or the same material as the body is made of.

In a preferred embodiment at least a part of the steering part can be separated from the body and preferably the steering part is formed in a separate socket which is being fastened to the body of the gateway before use. Also in a preferred embodiment the interface comprises an injection needle.

In a preferred embodiment the part of the steering part which can be separated from the body functions as an adapter for a given drug delivery device.

According to the invention a separate interface can be secured to the delivery device. Preferably the separate interface can be moved from one position where it covers the injection needle to a second position where the injection needle is not covered.

The present invention also concerns a system comprising a drug delivery device with an insertion needle secured to an interface wherein an end of the interface which is not secured to the drug delivery device is provided with at least one cover in order to provide a protected and sterile environment around the insertion needle. Preferably the drug delivery device is filled with a drug in a ready-to-use condition.

The present invention also concerns a gateway for subcutaneous injection of fluid, which gateway comprises

- a body with at least one through-going opening with an entrance and an outlet, and at least one cannula placed in fluid connection with the through-going opening and having a proximal end protruding from the lower side of the body;
- and at the entrance of the through-going opening medication can be injected by a delivery device which delivery device has protruding parts covering the entrance when delivering medication to the gateway and which protruding parts form an inner opening with a diameter d_i;

wherein the surface of the entrance is shaped in such a way that the cross-section of the top part of entrance, i.e. from the top of the entrance to a position $d_i/3$ below the top, do not exceed d_i. Preferably the surface of the top part is constructed as a part of a sphere. Alternatively the surface of the top part is constructed of several smaller plane surfaces connected to each other in angles above 90° forming a coherent, convex surface (multifaceted).

In a preferred embodiment the gateway has at least two through-going openings. Preferably at least one of the through-going openings has a wall

which can not be penetrated by a pointy insertion needle placed opposite the entrance for the insertion needle.

Preferably the septum can be either pushed away from the entrance of a through-going opening or penetrated in order to enter a through-going opening.

Embodiments of the invention will now be described with reference to the figures in which:

Figure 1 is an exploded view of a gateway.

Figure 2 is a cut-through drawing of the same embodiment as in figure 1.

Figures 3A and 3B show an embodiment of an inserter for the gateway of figs. 1 and 2 in an exploded view.

Figure 4 shows a second embodiment of a gateway according to the invention where the gateway is provided a cover.

Figure 5 shows the second embodiment of the gateway together with an injection needle.

Figure 6A shows a third embodiment of the gateway together with deep tracks and a corresponding injection needle.

Figure 6B shows two possible track patterns in the body of the gateway of the embodiment in fig. 6A.

Figure 7 shows a fourth embodiment of a gateway according to the invention where the gateway is provided with low tracks.

Figure 8 shows a fifth embodiment of a gateway according to the invention where the surface of the body of the gateway is completely smooth.

Figure 9 shows a sixth embodiment of a gateway according to the invention where the gateway is provided with both internal and external steering parts.

Figure 10 shows a second embodiment of an inserter part according to the invention.

Figure 11 shows an embodiment of an inserter for the gateway of fig. 10.

Figure 12 shows an embodiment of an adaptor for a drug delivery device with no injection needle.

Figures 13 and 14 show an embodiment of the gateway according to the invention having two trough-going openings.

Figure 15 shows an embodiment of the gateway having an entrance for a blunt needle.

Figure 16 shows another embodiment of the gateway according to the invention having two trough-going openings.

Figure 17 shows an embodiment of the gateway where the cross-section of the top part of the entrance do not exceed d_i.

Figure 18 shows an embodiment of the gateway where the cross-section of the top part of the entrance do not exceed d_i which embodiment is also easy to keep clean.

Figure 19 shows two separate interfaces for positioning between the delivery device and the gateway.

Figure 20 shows an embodiment of an interface integrated with the delivery device which interface has two positions, A and B.

Figure 21 shows another embodiment of an interface integrated with the delivery device which interface has two positions, A and B.

Figure 22 shows an embodiment of a selected interface positioned between the delivery device and a selected socket 36 in the gateway.

Figure 23 shows another embodiment of a selected interface positioned between the delivery device and a selected socket 36 in the gateway.

Figure 24 shows an embodiment of an interface or adaptor used for a prefilled syringe.

In figure 1 is shown an exploded view of a gateway. The gateway comprises a body 1 with a smooth distal surface, where the distal surface is the surface turned away from the patient after the gateway has been inserted, and at the proximal side of the body 1 is placed a mounting pad 2 having an adhesive surface proximal to the patient. The proximal side is the side turned towards the patient after the gateway has been inserted. The body 1 has a through-going opening 6 in which is placed a cannula 3 extending from the proximal side of the body 1. At the distal end of the cannula the diameter is increased which results in the forming of a small chamber 7 at this end of the cannula, this chamber functions as a deposit for fluid injected through the septum. In the through-going opening 6 is also placed a septum 4 which limits access to the opening 6 as the opening created in the septum 4 by a needle will be closed after removal of the needle due to the characteristics for the material chosen for the septum 4. It is necessary to use a relatively hard needle to penetrate the septum, but the needle does not need to be pointy. Relatively hard means that the needle has to be harder when compared to the material of the septum 4, the needle does not need to be made of steel; it could be made of e.g. hard plastic. In EP 1191964 it is described how to produce such a needle. At the distal end of the through-going opening 6, i.e. the end where the injection needle enters the opening 6 is placed a steering part 5; the steering part 5 is made of a relatively hard material and makes it easier to enter the needle into a correct position in the through-going opening 6. That the steering part is made of a relatively hard material means that it should not

be possible to penetrate the steering part 5 by the injection needle, how hard the material needs to be then depends on which injection needle is used. Materials which could withstand penetration from commonly used pointy injection needles would be a hard plastic or a metal but if the injection needle is blunt it would be possible to use softer materials like rubber.

Figure 2 shows a cut through the same embodiment of a gateway as shown in fig. 1. In this figure the mounting pad 2 is placed adjacent to the body 1. The cannula 3 is placed at the proximal end of the opening 6; adjacent to the cannula above the chamber 7 the septum 4 is placed. The steering part 5 is placed between the septum and the outer distal surface of the body 1. In this figure it is possible to see how the steering part 5 directs the needle into the correct position on the opposite side of the septum 4 and assures the injected fluid is placed in the chamber 7.

Figures 3A and 3B show an inserter device which can be used in accordance with the invention. The inserter comprises a housing 10, in this embodiment the housing 10 comprises two fastening elements 11 which assures that the insides 13 cannot rotate in relation to the housing. The housing also comprises detaining elements 12 in the form of two protruding parts keeping the insides 13 in a biased position until the insides 13 are released from the biased position by affecting some release means. The insides 13 are constructed of a central part 14 and a surrounding part 15. The central part 14 functions as a finger grip and the surrounding part 15 functions as a biasing unit. The central part 14 can slide between a forward and a retracted position in relation the housing 10 and the body 1 of the gateway is fastened to the central part 14. The surrounding part 15 is constructed as two parts formed almost as semicircles, where one end of each semicircle is attached to one of the fastening elements 11 in the housing 10, and the other end of each semicircle is - via a connecting wall 16 - fastened to the central part 14. The end of the semicircle fastened to the housing 10 at the fastening elements 11 does not move relatively to the housing 10 during use. The other

end of the semicircle which is attached to the central part 14 with the finger grips will move relatively to the housing 10 when the central part 14 is pulled out of the housing 10 (arrows for direction in fig. 3B). When pulling in the central part 14, the surrounding part 15 which functions as a biasing unit, will be tightened. The surrounding part 15 is kept in the biased position by two protrusions 17. The protrusions 17 are in this embodiment attached to the connecting wall 16 but could just as well be attached to the central part 14. When the central part 14 is pulled out of the housing 10, the protrusions 17 will be pulled past the detaining elements 12 and these elements will prevent the protrusion 17 - and therefore also the central part 14 - from returning to the relaxed position inside the housing 10.

As the housing 10 possesses certain flexibility the biasing position can be released by pressing on the sides of the housing at a line perpendicular to the line formed by the two detaining elements 12 (direction indicated by arrows on fig. 3A and 3B). When pressing at the two opposite sides in this position, the resulting deformation of the housing will cause the two detaining elements 12 to be pushed away from each other, thereby leaving enough room for the protrusions 17 to pass by the detaining elements 12 and for the central part 14 to be forced back into the relaxed position by the biasing unit 15.

The body 1 of the gateway is positioned at the proximal end of the central part 14. In the embodiment shown in fig. 3A and 3B the means 18 for engaging of the body 1 of the gateway has the form of a cupola. The body 1 of the gateway is placed with its distal side fitted into the cupola 18. The proximal side of the body 1 is covered with a mounting pad 2 and at least one insertion needle which is either attached to the central part 14 or to the body of the gateway protrudes from the proximal side through the mounting pad 2 when the body 1 is fastened to the inserter device 10, 13. If the insertion needle is attached to the inserter device 10, 13 the body 1 is provided with a cannula 3, preferably of a soft material.

When the injection prepared gateway is acquired by the user, the gateway will be placed in the inserter device and the whole unit will be sterilized. When the unit is sterilized it is necessary to provide the housing 10 with a removable cover on both the distal and the proximal end. The biasing unit 15 is in a relaxed state which means that the insides 13 is completely covered by the housing 10 while the insertion needle protrudes from the proximal side and requires a suitable cover which do not allow penetration by the sterile needle, preferably a relatively hard cover.

When the user is going to insert the gateway, the user first remove the two covers at the distal and the proximal end of the housing 10 and then the user removes the release liner of the mounting pad 2, if the mounting pad 2 is covered by a release liner. Afterwards the user grab the finger grip of the central part 14 and pull the central part 14 out of the housing in direction along the axis of the central part 14. The user pull until the protrusions 17 pass over the detaining elements 12 and a click is heard. The user then let go of the finger grip and leave the central part 14 in the tightened position. Now the injection prepared gateway is placed on the skin of the patient and the biasing unit 15 is released by squeezing lightly on the sides of the housing 10. It is marked by colorization or patterns where exactly on the housing 10 the user needs to squeeze in order to release the biasing unit.

When the biasing unit is released, the central part 14 moves back into the relaxed position inside the housing and because the insertion needle protrudes from the housing in the relaxed position, the insertion needle penetrates the patients' skin. When the insertion needle has penetrated the patients' skin, the inserter device 10, 13 is separated from the body 1 of the gateway and removed. The insertion needle will be removed together with the inserter device 10, 13 if the insertion needle is attached to the central part 14 but if the insertion needle is attached to the body of the gateway, the insertion needle will stay inserted and function as the cannula.

Other inserter devices than described here can be used together with the gateway according to the invention but it is necessary that it is possible to adapt the body of the gateway into the inserter devices and to keep it in position by preventing rotational movements until insertion has taken place. This can be difficult as the gateway preferably has a very smooth distal surface. This is contrary to the inserters for infusion sets as infusion sets comprises two parts: an infusion part which comprises a cannula being inserted in the patient's skin and a connector part. Because at least a part of the distal surface of the infusion part of an infusion set is provided with means for fastening the infusion part to the connector, the infusion part will always be provided with means for fastening the device inside an inserter.

In the above described inserter device 10, 13 the body 1 of the gateway is retained in the inserter device 10, 13 by the frictional resistance between the insertion needle and the cannula but there are other ways of retaining the body 1 of the gateway in the inserter device during insertion for example by applying an adhesive between the inserter device 10, 13 and the gateway, or by pressing the gateway into a restricted room formed by parts of the inserter device 10, 13. In order to assure it to be possible to disengage the gateway from the inserter device 10, 13 without the user having to somehow pull the gateway away from the inserter, the adherence between the inserter device 10, 13 and the gateway has to be smaller than the adherence between the mounting pad of the inserted gateway and the skin of the patient.

The present invention is directed especially to the use of both relatively short pointy needles as for example needles traditionally used in injections pens or blunt needles. For these two types of needles the steering part 5 assures a perfect entrance into the through-going opening 6 even for users without experience. The steering part 5 can be a very small unit placed inside the opening 6 and being flush with the distal surface of the body 1. In this case the distal surface of the body 1 can be made totally smooth without any protrusions or recesses which would be an advantage as it is very important

that the body 1 do not unintentionally stick to or get caught of anything as the patient moves around. Alternatively the steering part 5 can be formed externally on the body 1 in the form of tracks corresponding to the needle unit used for injection. This form of the steering part 5 has the advantage of giving very easy and secure injections as the external steering part 5 assures there will be only on way to put the injection needle when injecting medication to the patient through the gateway.

If a blunt needle is used for injection of medication the septum 4 will most likely has to have a preshaped hole in order for the blunt needle to be able to pass through, although it will depend on the material used to make the septum 4. If the insertion needle is fastened unreleasably to the inserter device 10, 13 a preshaped hole will be formed in the septum 4 when the inserter device 10, 13 and the insertion needle attached hereto is removed after insertion.

Figure 4 shows a cut through a gateway. In this embodiment the steering part 5 is formed as a central part of the body 1 is constituted of several upright parts or one coherent preferably circular part extending from the plan approximately parallel to the patients skin. In order for the gateway not to catch on to anything when attached to the patient, the gateway is provided with a cover 19. The cover provides the body 1 of the gateway with a smooth surface, and the cover 19 can also function as an adapter or interface, if the patient wants to use different types of needle units, if the cover 19 is formed as a ring which do not completely cover the through-going opening 6 of the body or is provided with a penetrable material above at least a part of the opening 6.

Figure 5 shows the same gateway as in figure 4 but now the cover 19 is removed from the gateway and the gateway is ready for injection of medication. The medication is injected with a syringe 20 provided with a pointy injection needle 21. In this embodiment the injection needle is

retracted compared to the front part of the syringe. The front part of the syringe comprises one or more projecting parts 22, these parts are protecting the surroundings from the pointy needle before and after injection and are also corresponding to the steering part 5. The correspondence between the steering part 5 and the projecting parts 22 assures easy and secure injection because it is only possible to place the injection needle in the correct position when the steering part 5 and the projecting parts 22 have to fit together.

Figure 6A shows a gateway where the steering part 5 is formed as a circular recess in the distal surface of the body 1 or holes placed in a circle. Two of the possible patterns of recesses are shown in figure 6B where the recesses forming the steering part 5 are shown from above.

Figure 7 shows yet another gateway where recesses of the steering part 5 are less deep and the protruding parts 22 of the needle unit 20 are influenced by one or more spring units 23. The spring units are pushing the protruding parts 22 down when they are in a relaxed position and are in this position protecting the surrounding from the needle 21. When the user wants to inject fluid into the gateway, the needle unit 20 with protruding parts 22 is placed in the steering part 5 and pushed down, this makes the projecting parts 22 disappear partly up in to the room where the spring units 23 are positioned. When pushed down the injection needle 21 extends beyond the projecting parts 22 and the needle 21 will penetrate the septum 4 and fluid is transferred to the cannula 3.

Figure 8 shows an embodiment of the gateway where the projecting parts 22 are formed as a cupola and the steering part 5 is the smooth distal surface of the body 1. This embodiment is also provided with springs 23 above the projecting parts 22. This makes the needle unit 20 more secure to handle before and after injection as there is no immediate access to the pointy needle 21.

Figure 9 shows an embodiment where the steering part 5 is placed both inside the opening 6 and formed as the upright walls of the body 1. Also the steering part 5 is built of different components and possibly different materials as the form defining the steering part 5 is partly comprised by the surface of the upright walls of the distal surface of the body 1 and partly of the top surface of an internal element 8 which is placed inside the through-going opening 6.

Figure 9 also shows to round adapters or interfaces 9. These adapters 9 can be placed on top of the upright central part of the body 1 and can make it possible to use different kinds of needles or needle systems while still using the same gateway.

Figure 10 shows yet another embodiment of a gateway. In this embodiment the through-going opening 6 of the body 1 is situated almost parallel to the skin of the patient when the gateway has been inserted. The gateway according to this embodiment can be injected in an angle from approximately 0° - or the angle in which the gateway is supposed to stay after insertion - to approximately 90°. No matter from which angle the gateway is injected, it is after injection laid down on the proximal side and secured to the skin by the mounting pad (2).

Figure 11 shows an embodiment of an inserter part adapted for the embodiment of the gateway shown in figure 10. This embodiment comprises a housing 10, a biasing unit 15 and a central part 14 which can slide between a forward and a retracted position. In fig. 11 the central part 14 is in a forward position and the biasing unit 15 is relaxed. The central part 14 is provided with a detaining element 12, and when the central part 14 is in a retracted position where the biasing unit 15 is tightened, the detaining element 12 will rest against a protrusion on the internal side of the upper side of the housing 19 ("upper side" refers to the upper side of the housing 10 as seen in figure

11). Also the central part 14 is provided with means 18 for engaging the body 1 of the gateway.

Preferably the gateway system according to this embodiment is delivered to the user with the biasing unit 15 in a tightened state i.e. where the central part 14 is in a retracted position. When the user is going to insert the gateway, the user first remove a cover which has kept the gateway system sterile and then the user removes the release liner of the mounting pad 2, if the mounting pad 2 is covered by a release liner. Afterwards the user places the forward end of the inserter part against the skin in the desired insertion angle. The user then pushed the release means marked with and arrow in fig. 11. The release means pushes down the detaining element 12 and releases the biasing unit 15. The central part 14 and the gateway is pushed forward where the penetrating needle penetrate the skin of the patient and inserts the cannula 3. After insertion of the cannula 3 the inserter part is removed from the gateway and the mounting pad 2 secured to the skin.

In figure 12A and 12B is shown an embodiment of a gateway which has to possible injection positions: a first injection position is from the top where a drug delivery device as shown in fig. 5 can be used, and a second injection position is through the wall forming the steering part 5.

In fig. 12A the protecting cover of the gateway is removed and the gateway is ready for injection from the top. In fig. 12B the cover is replaced with an adaptor which adaptor makes it possible to use a drug delivery device without an injection needle. The adaptor 30 comprises a steering part 5a with upright walls surrounding an upright needle 31 which can penetrate a septum in a drug delivery device. From the needle 31 the fluid medication flows through a pipe 32, the fluid passes an opening in the wall of the body of the gateway provided with a seal ring 33, and enters the cannula 3 through and opening 34 in the sidewall of the cannula 3. In order to assure correct

position of the adaptor 30 the wall of the body of the gateway is provided with a recess of which a side wall 35 is shown in fig. 12A.

Fig. 13 and 14 show an embodiment of a gateway which, like the embodiment of fig. 12, has two possible injection positions: a first injection position 40 is positioned at the central top of the body 1 where a drug delivery device with a short pointy needle, normally max. 3 mm, can be used, and a second injection position 50 positioned at the peripheral top wall of the body 1 of the gateway where a drug delivery device with a long pointy needle, no maximum for the needle, can be used.

Fig. 13 shows the embodiment from above where the first injection position 40 is central and comprises relatively hard steering parts 45 surrounding the central opening 46. The second injection position 50 comprises a relatively large area of a septum 54 which can be penetrated by a pointy long needle in any position.

Fig. 14 shows a cut through the embodiment of fig. 13. When fluid is injected through the first injection position 40 the short injection needle is inserted through the opening 46 and penetrates the septum 44 of the first injection position and the medication is injected into the cannula 3 and the room 47 below the septum 44. As the pointy needle used for injecting the medication is short the risqué of penetrating the wall of the cannula 3 with the pointy needle is very small. When fluid is injected through the second injection position 50 the injection needle is inserted by penetrating the septum 54 of the second injection position and the medication fills the room 57 and flows through a passage into the cannula 3 below the septum 44. As the pointy needle used for injecting the medication, irrespective of where the septum 54 is penetrated, meets the hard material of the body 1 of the gateway when the needle is fully inserted, it does not matter how long the insertion needle is as the insertion length is defined by the depth of the room below the septum 54.

Figure 15 shows a cut through an embodiment of a gateway where the septum 4 is constructed of two sections, an upper section 4a and a lower section 4b, the two sections 4a and 4b might be molded as one coherent unit or it might be molded as to units which are fitted together in the through going opening formed in the body 1. In this embodiment a precut opening 4c is formed in the upper section 4a of the septum which makes it appropriate to use a blunt insertion needle 21 when delivering medication to the gateway. The precut slit is held in a closed position by compression as the septum 4 is press-fit into the body 1. When medication is to be delivered the blunt needle 21 of the delivery device is forced through the precut opening 4c until the blunt needle 21 meets the inclined walls of the lower section 4b of the septum, and then the drug is delivered into the cannula 3 area filling up at least part of the space inside the septum 4.

Figure 16 shows a cut through an embodiment of a gateway where two different kinds of delivery devices can be used. Fig. 16 A shows the central part of a gateway with the cylindrical septum 4 which, together with an O-ring 4d, are blocking the through going opening of the body 1 which in this embodiment is split up into two passages for fluids 6a and 6b. The O-ring 4d is positioned in a circular groove formed in the body 1.

In fig. 16 B it is shown how a blunt injection needle 21 can be used to deliver a drug to the gateway. This insertion needle 21 opens to the side and when pushed toward the septum 4 the insertion needle 21 compresses the septum 4 and cause a deformation of the septum. This deformation allows fluid to flow from the insertion needle 21 into the pass way 6b from where it can flow to the cannula (not shown). The O-ring 4d assures that no fluid passes between the injection needle 21 and the body 1 of the gateway while fluid is flowing out of the insertion needle 21.

In fig. 16 C it is shown how a pointy injection needle 21 can be used to deliver a drug to the gateway. This insertion needle 21 opens at the pointy

end and when pushed toward the septum 4 it penetrates the top of the septum and allow fluid to flow from the insertion needle 21 into the pass way 6a from where the medication can flow to the cannula (not shown). The O-ring 4d assures that fluid can not flow back between the septum 4 and the body 1 of the gateway while fluid is flowing out of the pointy insertion needle 21.

Fig. 17 shows an embodiment where the gateway is ready for injection of medication. The medication is injected with a syringe 20 provided with a pointy injection needle 21. In this embodiment the injection needle is retracted compared to the front part of the syringe. The front part of the syringe comprises one or more projecting parts 22, these parts protect the surroundings from the pointy needle before and after injection and correspond to the steering part 5. The correspondence between the steering part 5 and the projecting parts 22 assures easy and secure injection because it is only possible to place the injection needle in the correct position when the steering part 5 and the projecting parts 22 have to fit together. In this embodiment the steering part 5 provided by the body 1 and the septum 4 is partly formed as a sphere with a diameter corresponding closely to the inner distance d_i between the projecting parts 22 of the injection device. This form allows the injection device 20 to be guided into correct position from any horizontal direction i.e. 360° around the body of the gateway although the injection device 20 diverts approximately up to 45° from vertical.

Fig. 18 shows an embodiment of the gateway which is easy to keep clean and to clean while mounted on the skin of a patient. The body 1 of the gateway is formed with raised side parts which partly protect the raised center part and at the same time provide room for cleaning between the upright walls 5 and the raised sides of the body 1, also the edge between the upright walls 5 and the top provided by the septum 4 are rounded, preferably the top of the central part should be spherical.

Fig. 19 A and B show two embodiments of adaptors 30, such an adaptor is intended for being positioned between the gateway and the delivery device. The first adaptor shown in fig. 19 A has a pointy insertion needle 21 included, this insertion needle 21 is unreleasably fastened to the adaptor 30 and has a pointy proximal end 21a which end can penetrate a septum in a gateway (not shown) and a pointy distal end 21b which end can penetrate a septum in a delivery device 20. The second adaptor shown in fig. 19 B does not have a pointy insertion needle 21 included, this adaptor 30 is used together with a delivery device 20 having a pointy insertion needle 21.

Fig. 20 A and B show yet an embodiment of an adaptor 30. This embodiment of the adaptor 30 is fastened unreleasably to the delivery device 20 and the adaptor 30 has two secured positions, a retracted position as shown in fig. 20 A and forward position as shown in fig. 20 B. If the delivery device 20 is to be used to add medication to a standard gateway without steering parts 5 the adaptor 30 is in the retracted position of fig. 20 A when transferring medication from the delivery device 20 to the gateway. If the delivery device 20 is to be used to add medication to a gateway with steering parts 5 as shown e.g. in fig. 5 or 17 the adaptor 30 is in the forward position of fig. 20 B when transferring medication from the delivery device 20 to the gateway.

Fig. 21 A and B show an embodiment of a retrofit needle with projecting parts 22. The projecting parts 22 has two positions, a central position shown in fig. 21 A and a remote position shown in fig. x7 B. The retrofit needle 21 is first mounted on the syringe in the normal position while the projecting parts 22 is in the remote position (B), then the syringe is filled with medication. After filling the syringe the projecting parts 22 are moved to the central position (A) covering the needle and the medication can be injected into a gateway with steering parts 5 as shown e.g. in fig. 5 or 17.

Fig. 22 illustrates another embodiment of an adaptor 30. This embodiment of the adaptor 30 is intended to make a standard delivery device 20 fit with the

body 1 of a gateway being equipped with removable steering parts 5 placed in a socket 36 in the body 1 of the gateway. The socket 36 is pushed into the body 1 before use and a click noise will verify correct positioning.

When transferring medication from a source, e.g. a vial containing medication, to the patient, the delivery device 20 is first filled from the not shown source and during the filling process the delivery device 20 is not protected by the adaptor. After filling the delivery device 20 the adaptor 30 is either positioned on the delivery device 20 or in the socket 36 formed by the removable steering parts 5. When transferring medication to the patient the delivery device 20 is inserted into the adaptor 30, when the delivery device 20 is inserted into the adaptor 30 the insertion needle 21 penetrates the protective septum 4 covering the entrance to the cannula 3 and medication can be injected into the space 7 above the cannula 3 and flow into the blood stream of the patient.

Fig. 23 illustrates yet another embodiment of an adaptor 30. This embodiment of the adaptor 30 is also intended to make a standard delivery device 20 fit with the body 1 of a gateway being equipped with removable steering parts 5 placed in a socket 36 in the body 1 of the gateway.

This embodiment of the adaptor 30 has shorter arms adapting to the delivery device 20 compared to the embodiment of fig. 22.

Fig. 24 illustrates an embodiment of an adaptor 30 for a prefilled syringe. This embodiment of the adaptor 30 is placed in connection with a standard delivery device 20 before use. This system comprising a prefilled delivery device 20 is delivered to the user in the form illustrated in fig. 24, that the delivery device 20 is prefilled means that the user does not have to fill the device 20 him/her self as the delivery device 20 including the drug is handed to the user in ready-to-use condition which includes that the drug is in a ready-to-use form and the needle section of the device is sterilized. When the user is going to inject medication with the prefilled delivery device 20, the

cover 4a is first removed, then the delivery device 20 is positioned in or connected to the gateway or to another device ready for receiving medication and then the medication can be injected. Normally the delivery device 20 is a syringe.

Claims

1. A system comprising an inserter device and a gateway for subcutaneous injection of fluid where the gateway comprises a body (1) with at least one through-going opening (6), at least one cannula (3) and a restriction (4) for microorganisms placed at the distal end of the at least one cannula (3) or in the at least one through-going opening (6); and which system comprises at least one penetrating member having a proximal end protruding from the lower side of the body (1); drugs to be injected is delivered to the gateway by a drug delivery device (20) being able to pass the restriction (4) for microorganisms, the gateway is releasably connected to a biasing unit (15) in the inserter device (10, 13) which unit (15) can bring the gateway from a retracted to a forward position when released, **characterized in** that the gateway comprises a distal surface (1a) corresponding to a proximal surface (1b) integrated with the inserter device.

2. A system according to claim 1 **characterized in** that the proximal surface (1b) integrated with the delivery device (20) belongs to a separate interface (9, 30).

3. A system comprising an inserter device, a gateway and an interface (9, 30), where the gateway comprises a body (1) with at least one through-going opening (6), at least one cannula (3) and a restriction (4) for microorganisms placed at the distal end of the at least one cannula (3) or in the at least one through-going opening (6); and which system comprises at least one penetrating member having a proximal end protruding from the lower side of the body (1); drugs to be injected is delivered to the gateway by a drug delivery device (20) being able to pass the restriction (4) for microorganisms, the gateway is releasably connected to a biasing unit (15) in the inserter device (10, 13) which unit (15) can bring the gateway from a retracted to a forward position when released, **characterized in** that the interface (9, 30)

provides a distal surface corresponding to the inserter and a proximal surface corresponding to the gateway.

4. A system comprising a drug delivery device (20) and a gateway for subcutaneous injection of fluid where the gateway comprises a body (1) with at least one through-going opening (6), at least one cannula (3) and a restriction (4) for microorganisms placed at the distal end of the at least one cannula (3) or in the at least one through-going opening (6); and which system comprises at least one penetrating member having a proximal end protruding from the lower side of the body (1); drugs to be injected is delivered to the gateway by the drug delivery device (20) being able to pass the restriction (4) for microorganisms, the gateway is releasably connected to a biasing unit (15) in an inserter device (10, 13) which unit (15) can bring the gateway from a retracted to a forward position when released, **characterized in** that the system also comprises a separate interface (9, 30) comprising a proximal surface (1c) corresponding to a distal surface (1a) of the gateway and a distal surface (1d) corresponding to a proximal surface (1b) of the delivery device (20).

5. A system comprising an inserter device (10, 13), a drug delivery device (20) and a gateway for subcutaneous injection of fluid where the gateway comprises a body (1) with at least one through-going opening (6), at least one cannula (3) and a restriction (4) for microorganisms placed at the distal end of the at least one cannula (3) or in the at least one through-going opening (6); and which system comprises at least one penetrating member having a proximal end protruding from the lower side of the body (1); drugs to be injected is delivered to the gateway by the drug delivery device (20) being able to pass the restriction (4) for microorganisms, the gateway is releasably connected to a biasing unit (15) in the inserter device (10, 13), which unit (15) can bring the gateway from a retracted to a forward position when released, **characterized in** that the gateway comprises a distal surface (1a)

corresponding to a proximal surface (1b) integrated with the inserter device and to a proximal surface (1b) integrated with the delivery device (20).

6. A system according to claim 5, **characterized in** that the gateway comprises a distal surface (1a) corresponding to a proximal surface (1b) of an interface (9, 30) and the interface (9, 30) has a distal surface corresponding to a proximal surface (1b) of the delivery device (20).

7. A system according to claim 1-6, wherein the distal surface (1a) of the gateway comprises a steering part (5) constituted of one or more parts inserted in the opening (6) which part or parts are made of a relatively hard material for example metal or hard plastic or the same material as the body (1) is made of.

8. A system according to claim 1-6, wherein the steering part (5) comprises tracks (5) which tracks are formed as protruding or recessing elements compared to the main part of the distal surface.

9. A system according to claim 8, wherein the tracks (5) have the form of one or more recesses.

10. A system according to claim 8, wherein at least a part of the steering part (5) can be separated from the body (1).

11. A system according to claim 10, wherein the steering part (5) is formed in a separate socket (36) which is being fastened to the body (1) of the gateway before use.

12. A system according to claim 11, wherein the part of the steering part (5) which can be separated from the body (1) functions as an adapter for a given drug delivery device (20).

13. A system according to claim 11, wherein the interface comprises an injection needle (31).

14. A system according to claim 3 or 5, wherein a separate interface (30) is secured to the delivery device (20).

15. A system according to claim 14, wherein the separate interface (30) can be moved from one position where it covers the injection needle (21) to a second position where the injection needle (21) is not covered.

16. A system according to claim 1-14, wherein the gateway comprises means for releasably connecting a sensor device for measuring the glucose content of the blood.

17. A system according to claim 5, wherein the part of the inserter device (10, 13) being in contact with the body (1) of the gateway is shaped as the end of an injection pen.

18. A system according to claim 1-17, wherein a corresponding removable cover (19) can be positioned on top of the body (1) between injections.

19. A system according to claim 1-18, wherein the body (1) is made of a transparent material such as ABS, PP or PE.

20. A system comprising a drug delivery device (20) with an insertion needle (21) secured to an interface (30) **characterized in** that an end of the interface (30) which is not secured to the drug delivery device (20) is provided with at least one cover (4a) in order to provide a protected and sterile environment around the insertion needle (21).

21. A system according to claim 20, **characterized in** that the drug delivery device (20) is filled with a drug in a ready-to-use condition.

22. Gateway for subcutaneous injection of fluid, which gateway comprises

- a body (1) with at least one through-going opening (6) with an entrance and an outlet, and at least one cannula (3) placed in fluid connection with the through-going opening (6) and having a proximal end protruding from the lower side of the body (1);
- and at the entrance of the through-going opening (6) medication can be injected by a delivery device (20) which delivery device (20) has protruding parts (22) covering the entrance when delivering medication to the gateway and which protruding parts (22) form an inner opening with a diameter d_i;

characterized in that the surface of the entrance is shaped in such a way that the cross-section of the top part of entrance, i.e. from the top of the entrance to a position $d_i/3$ below the top, do not exceed d_i.

23. Gateway according to claim 22, wherein the surface of the top part is constructed as a part of a sphere.

24. Gateway according to claim 22, wherein the surface of the top part is constructed of several smaller plane surfaces connected to each other in angles above 90°.

25. Gateway according to claim 22, having at least two through-going openings.

26. Gateway according to claim 25, wherein at least one of the through-going openings (6) has a wall which can not be penetrated by a pointy insertion needle (21) placed opposite the entrance for the insertion needle (21).

27. Gateway according to claim 25, wherein a septum (4) covers a shared entrance of at least two through-going openings (6).

28. Gateway according to claim 25, wherein the septum (4) can be either pushed away from the entrance of a through-going opening (6b) or penetrated in order to enter a through-going opening (6a).

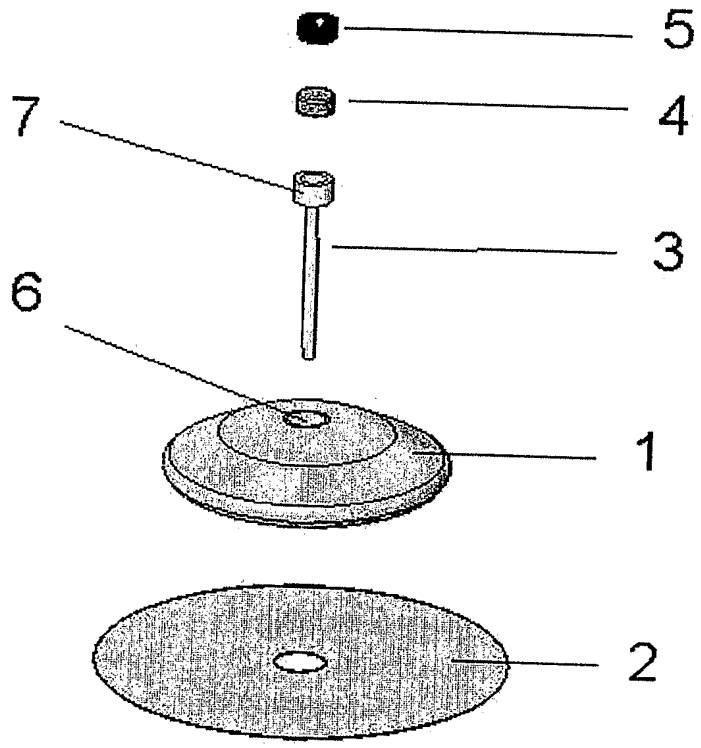


Fig. 1

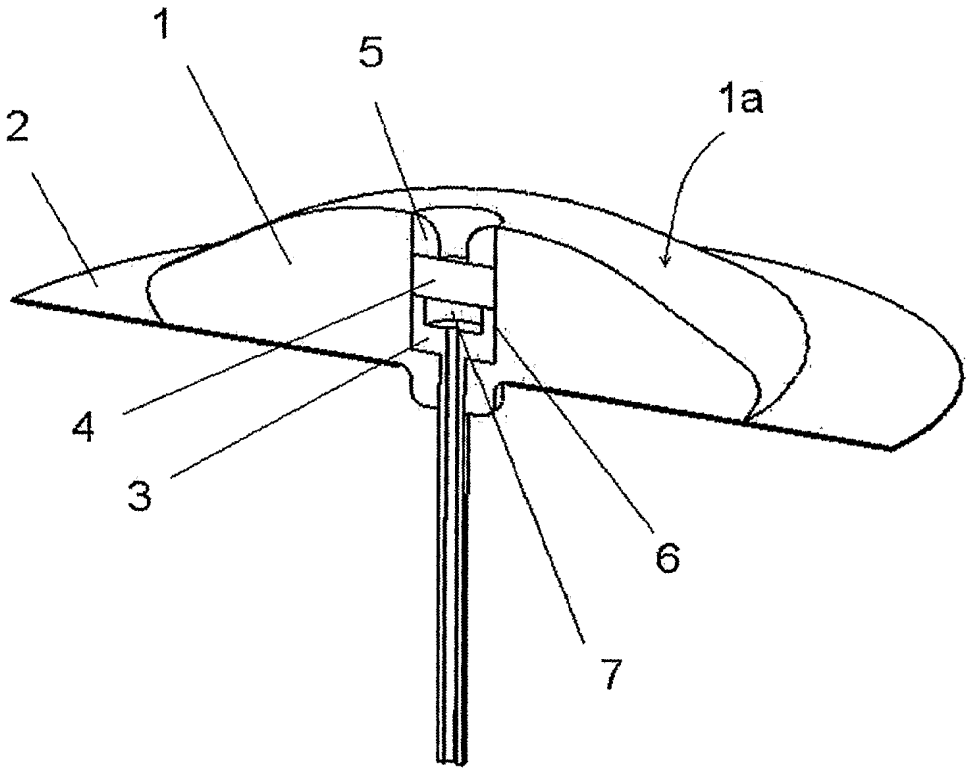


Fig. 2

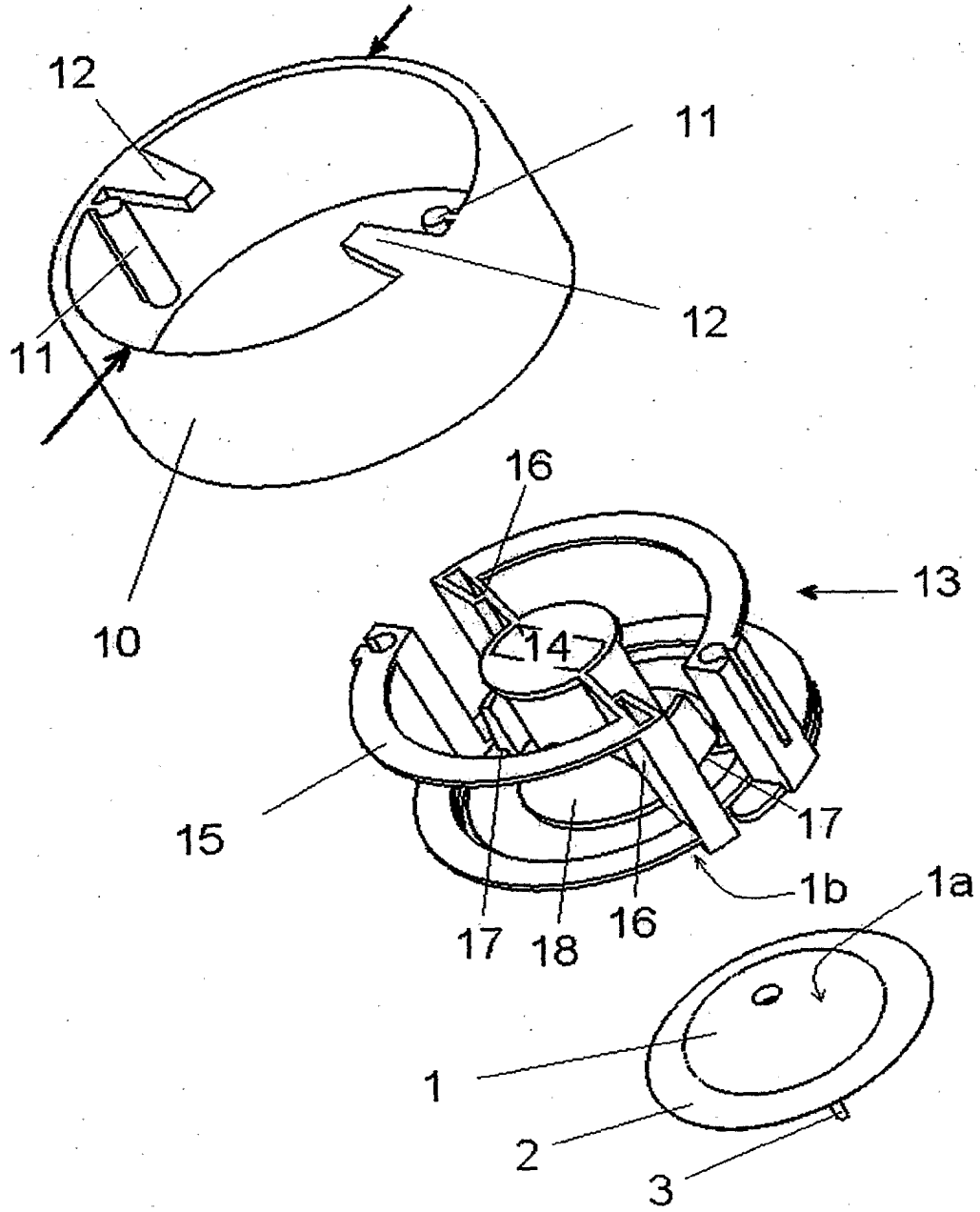


Fig. 3A

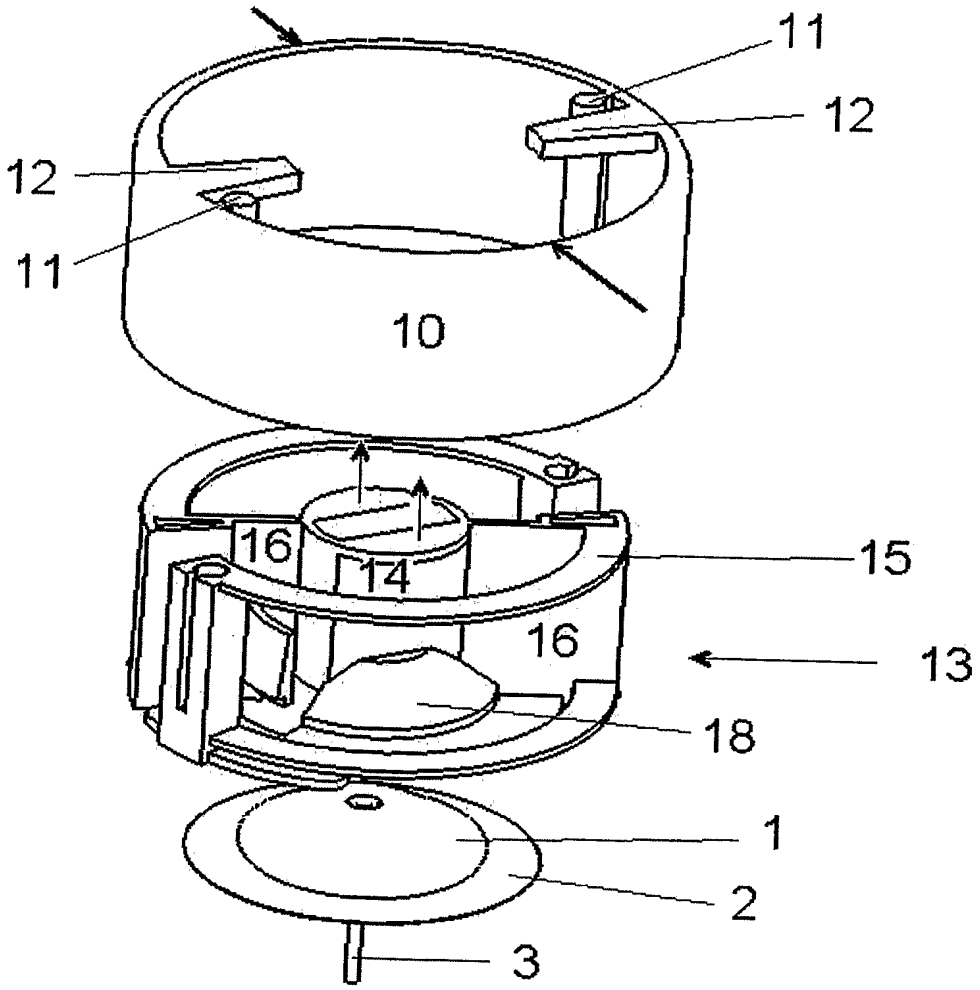


Fig. 3B

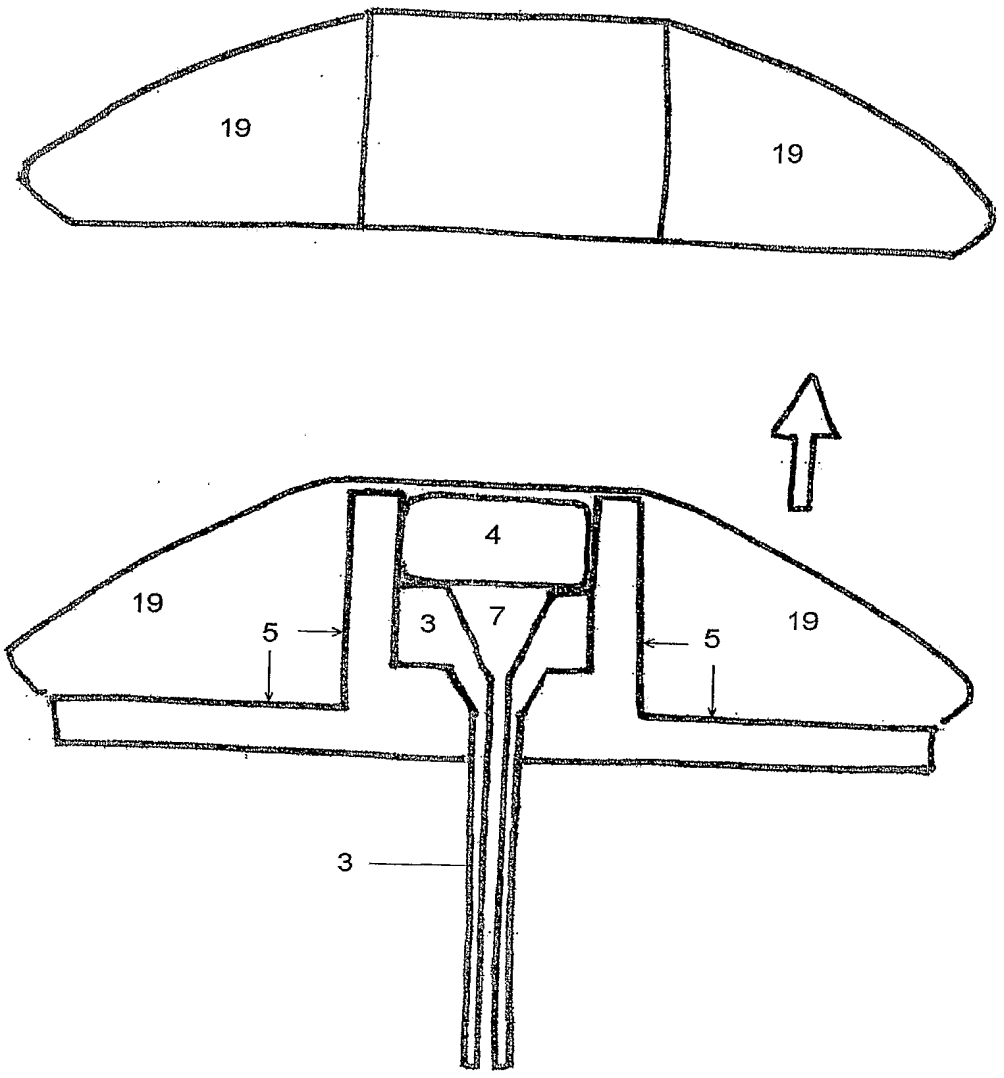


Fig. 4

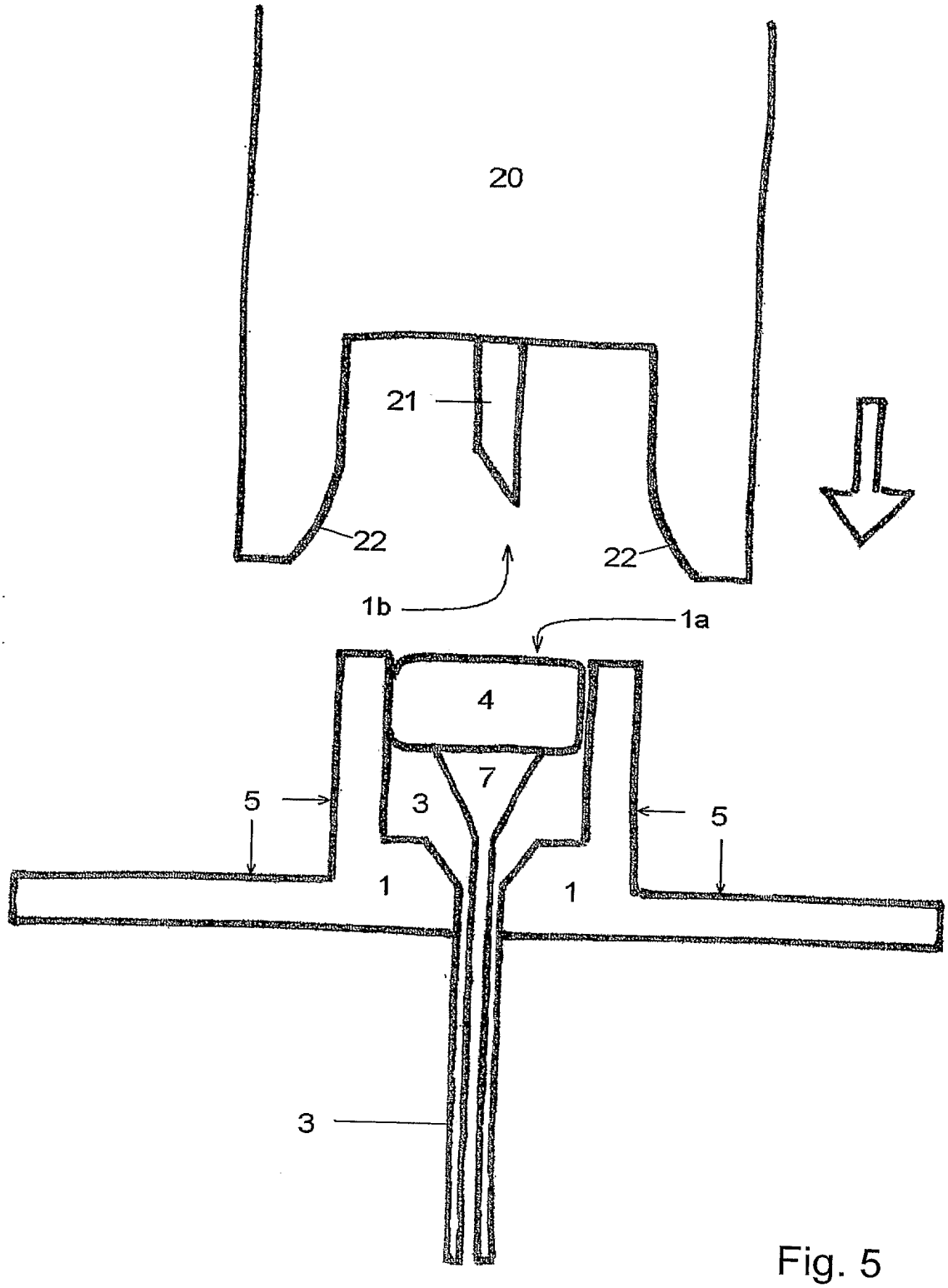


Fig. 5

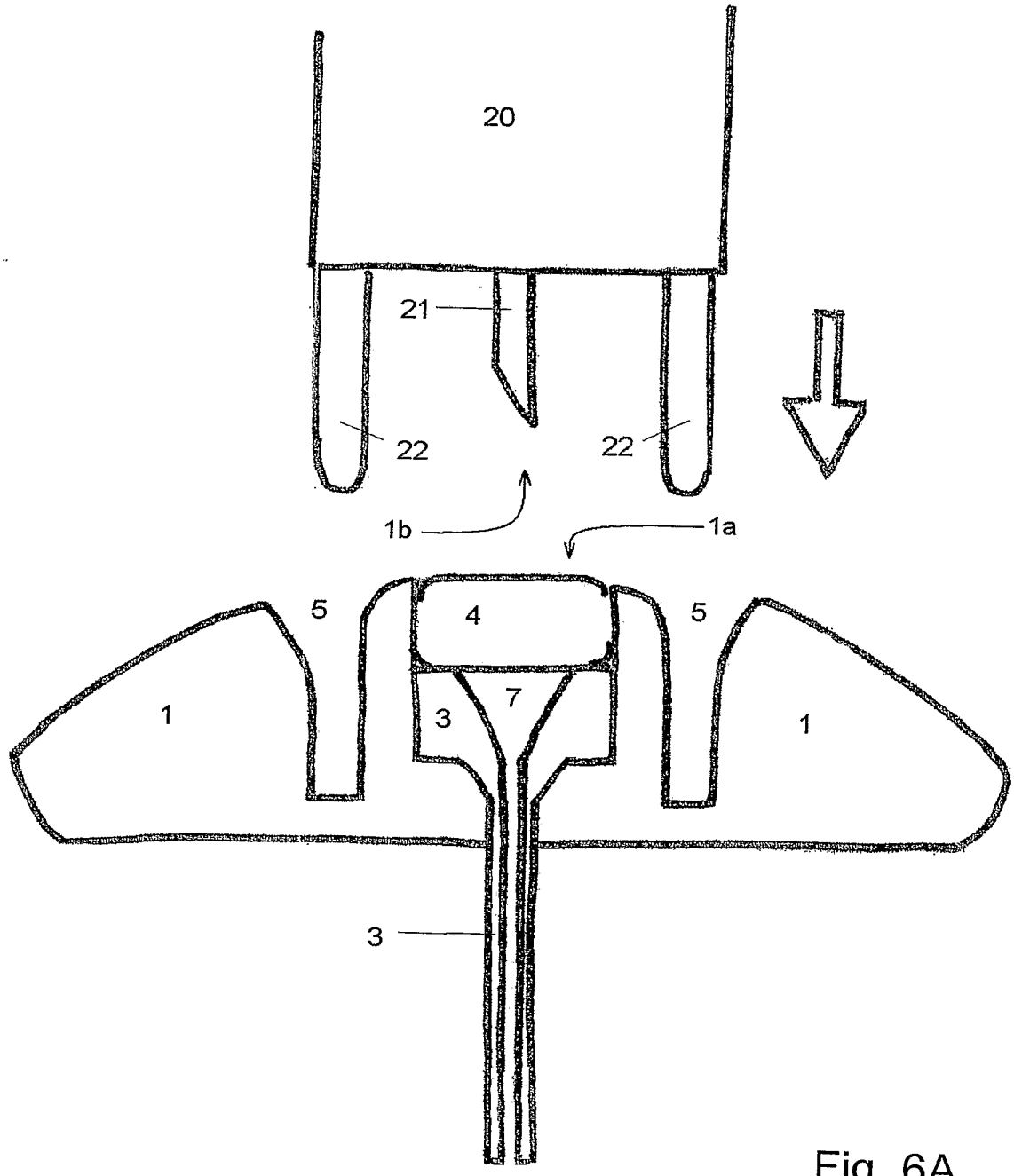


Fig. 6A

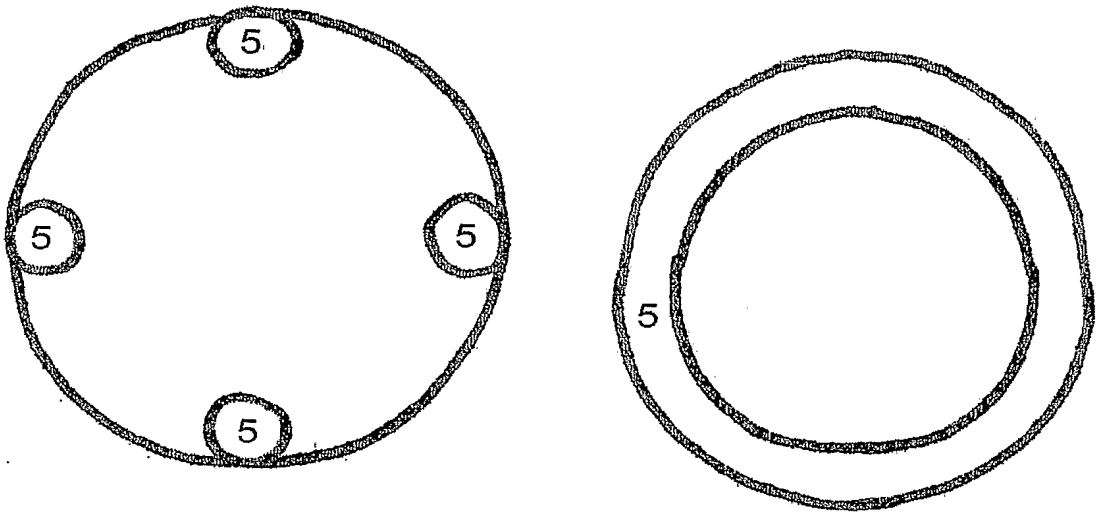


Fig. 6B

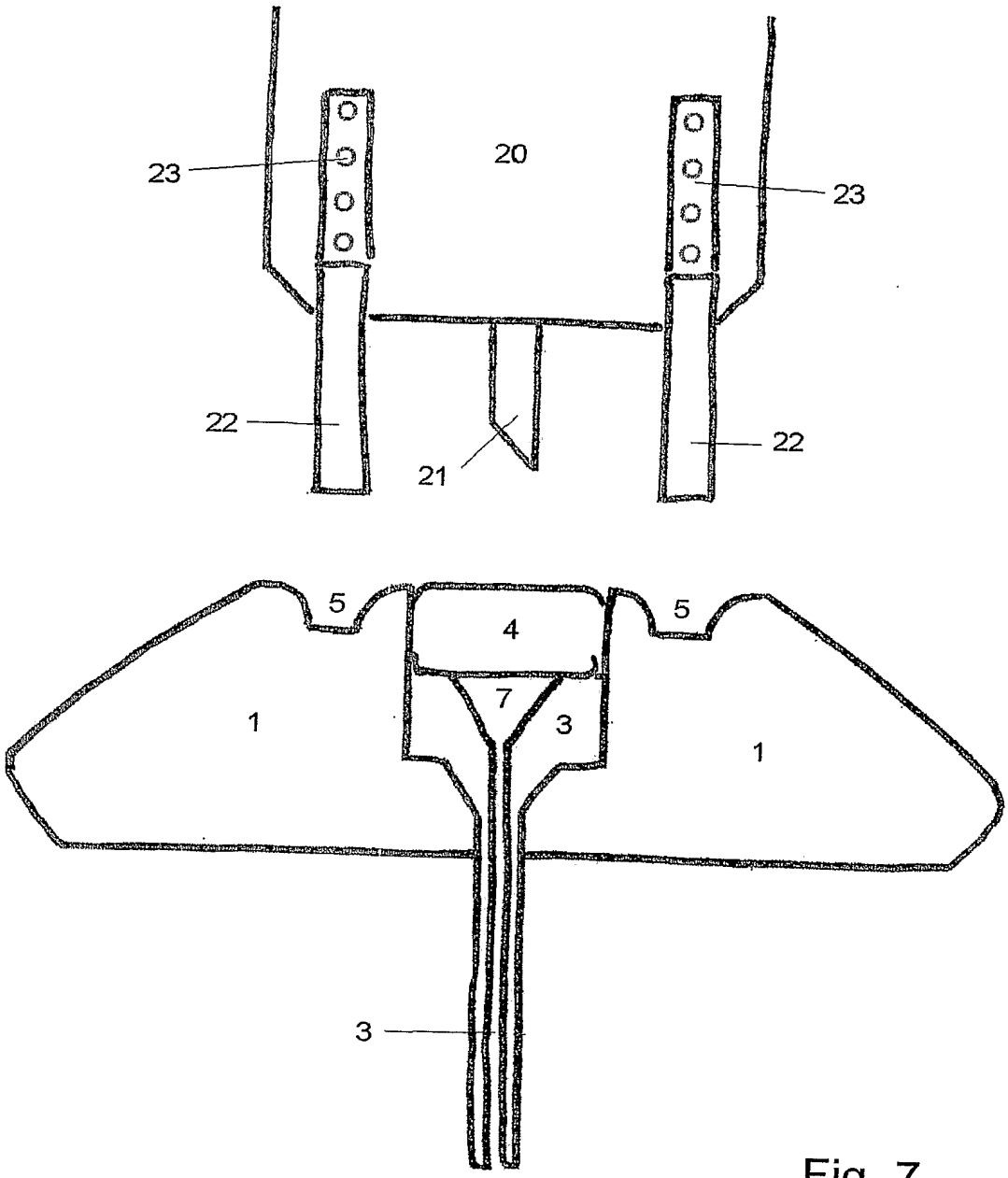


Fig. 7

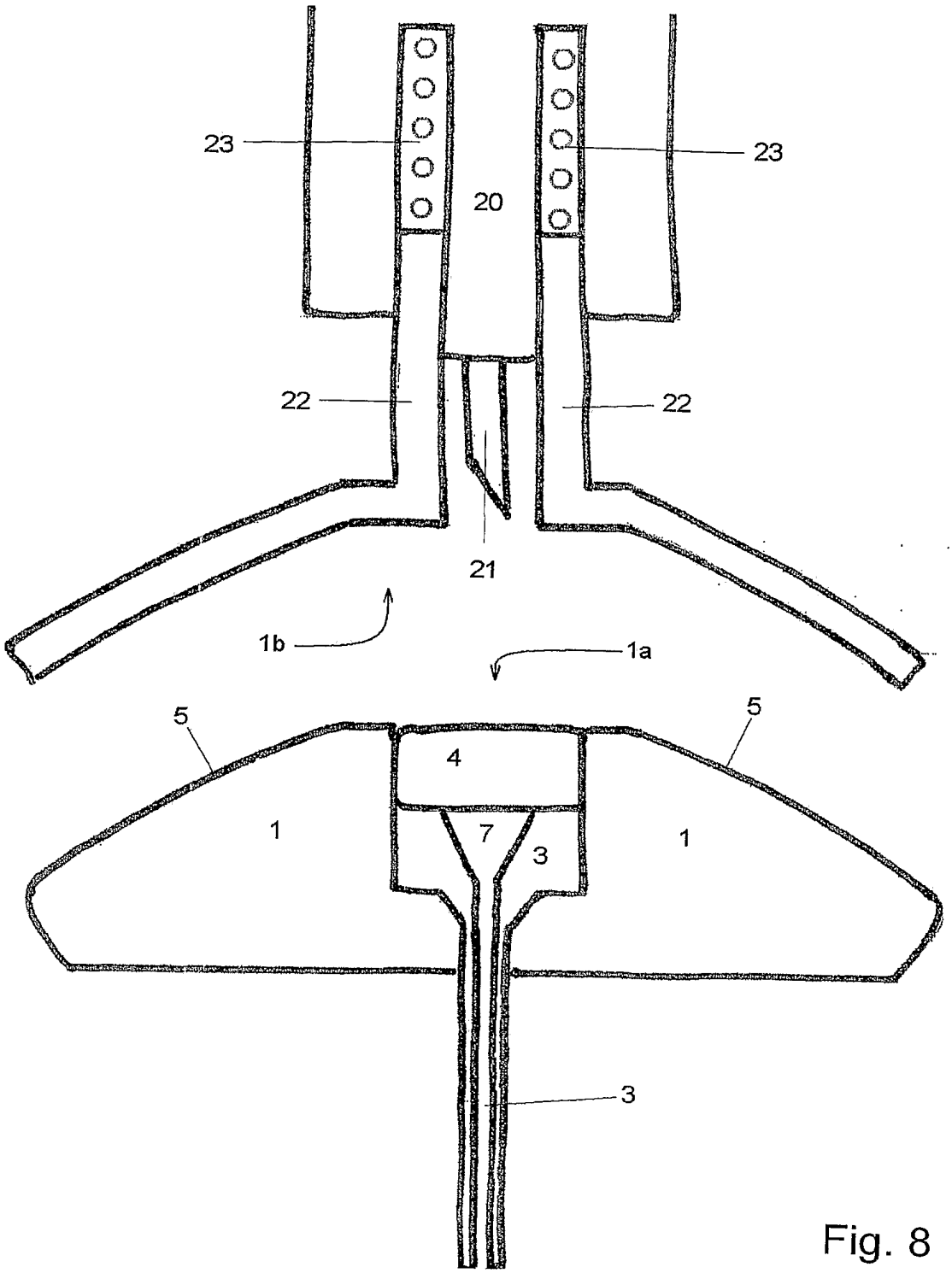


Fig. 8

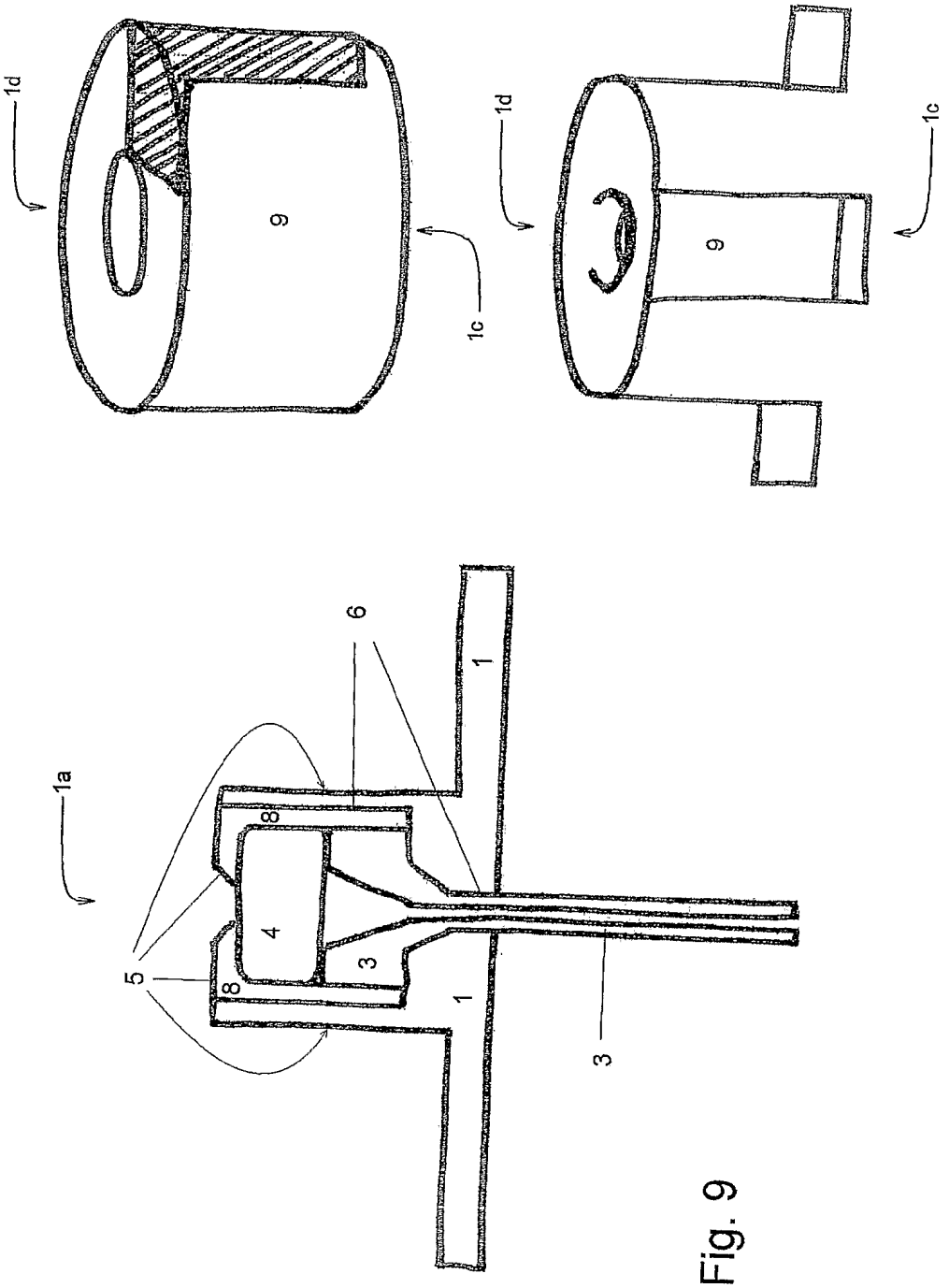


Fig. 9

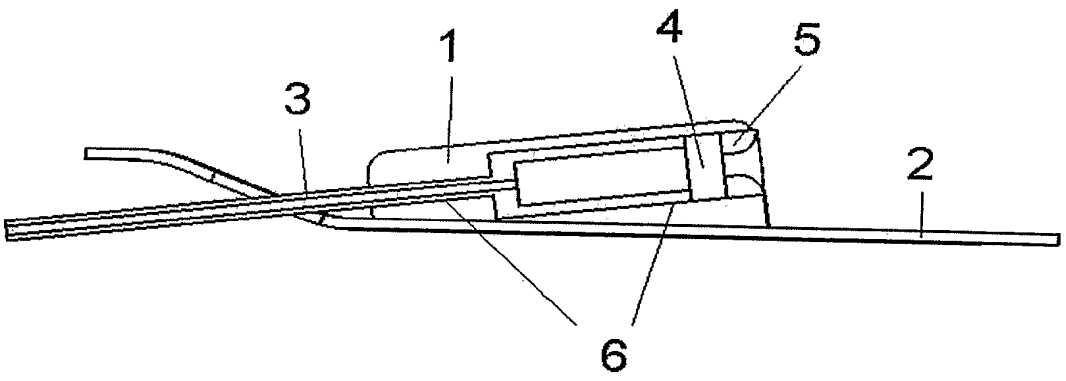


Fig. 10

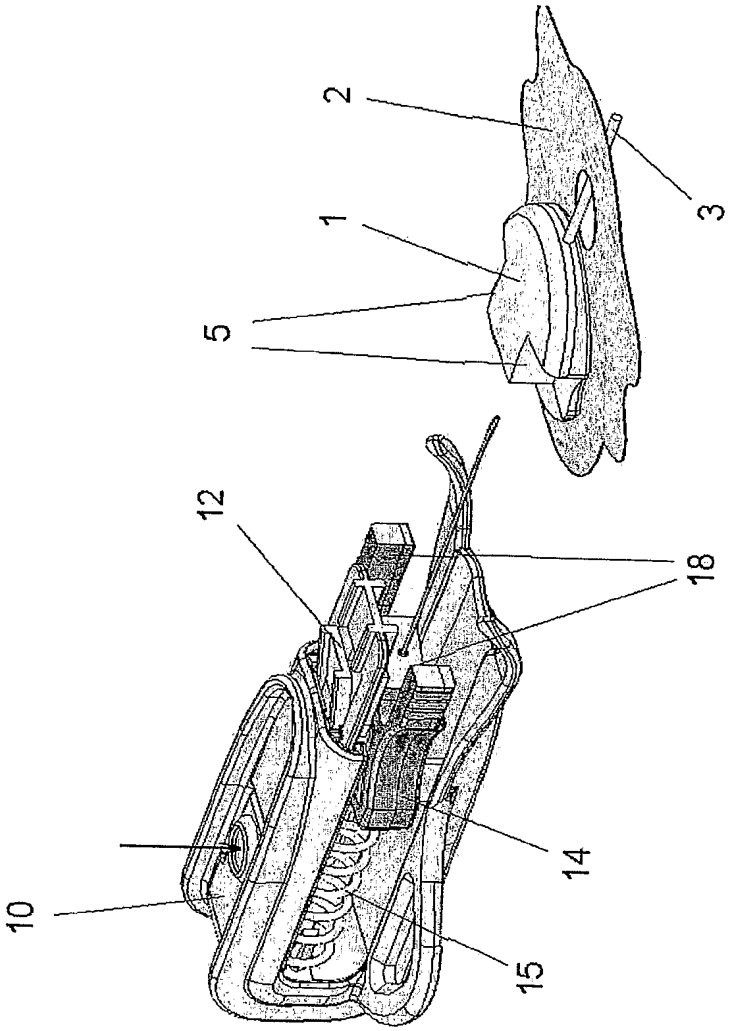


Fig. 11

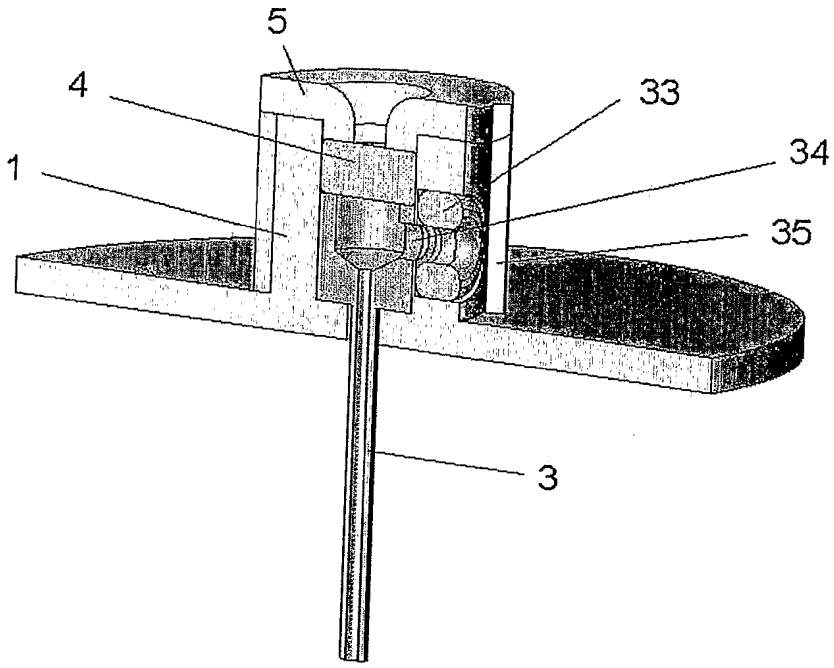


Fig. 12A

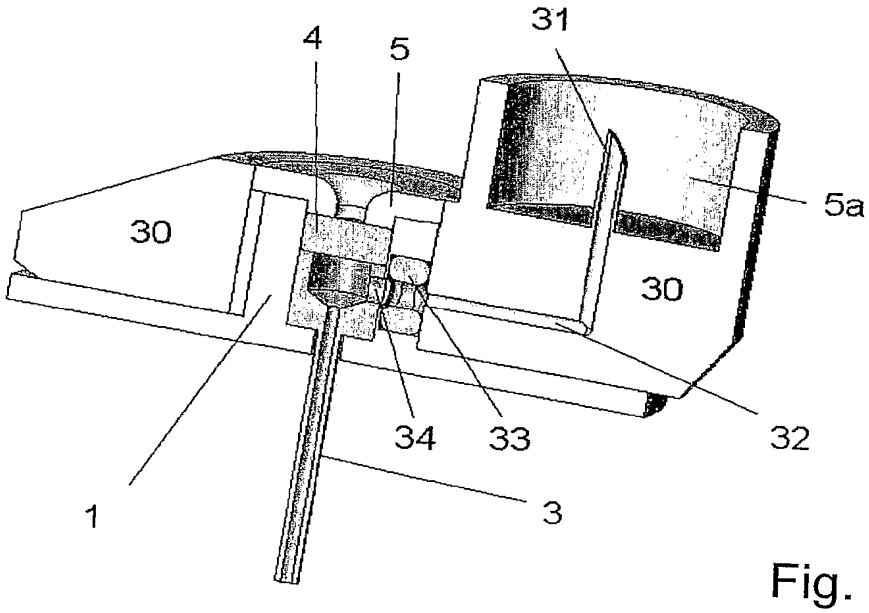


Fig. 12B

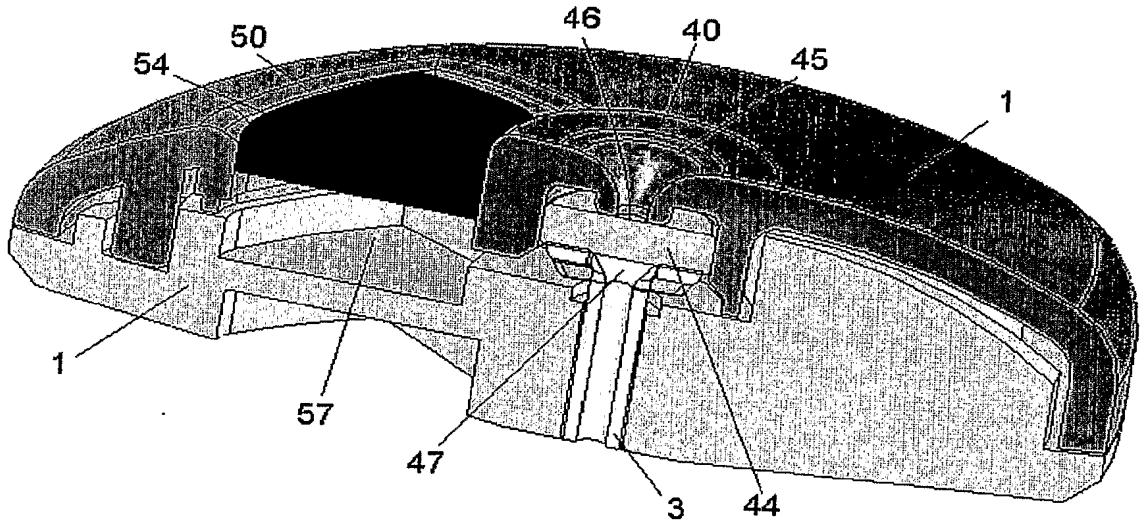


Fig. 13

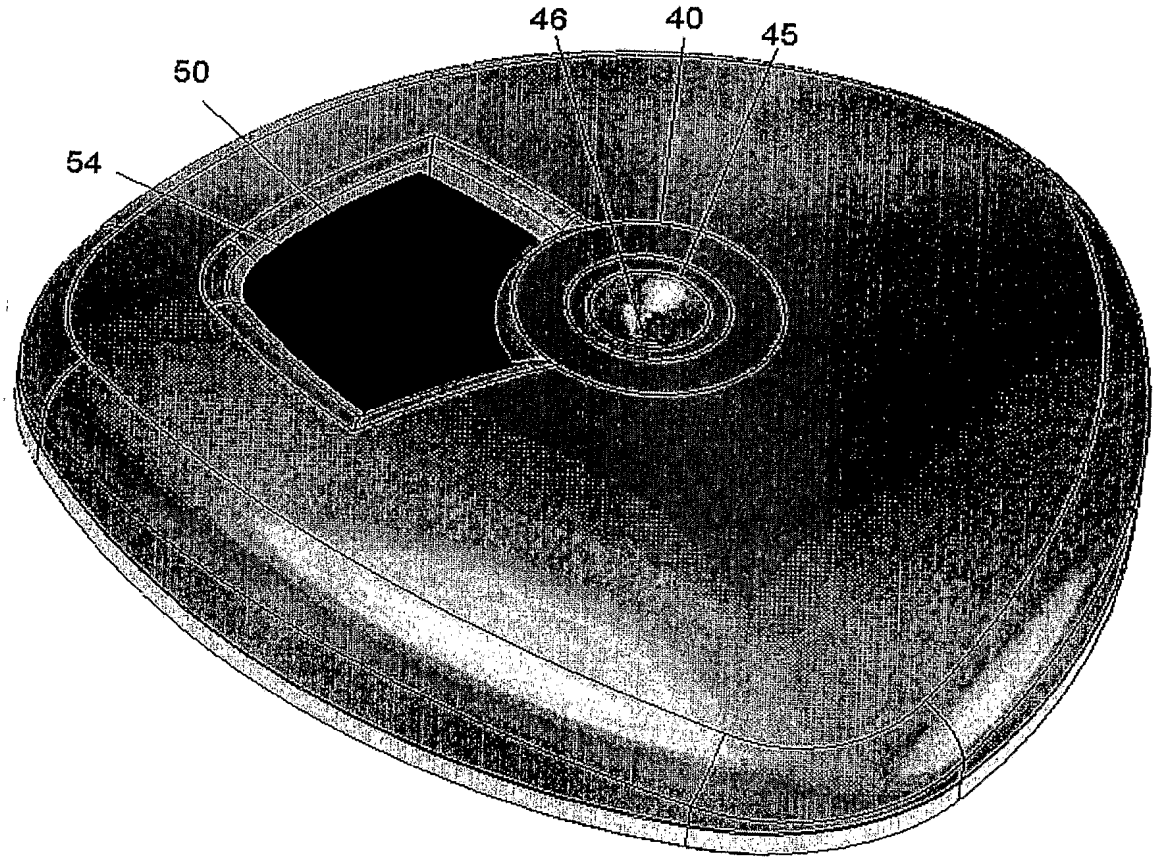


Fig. 14

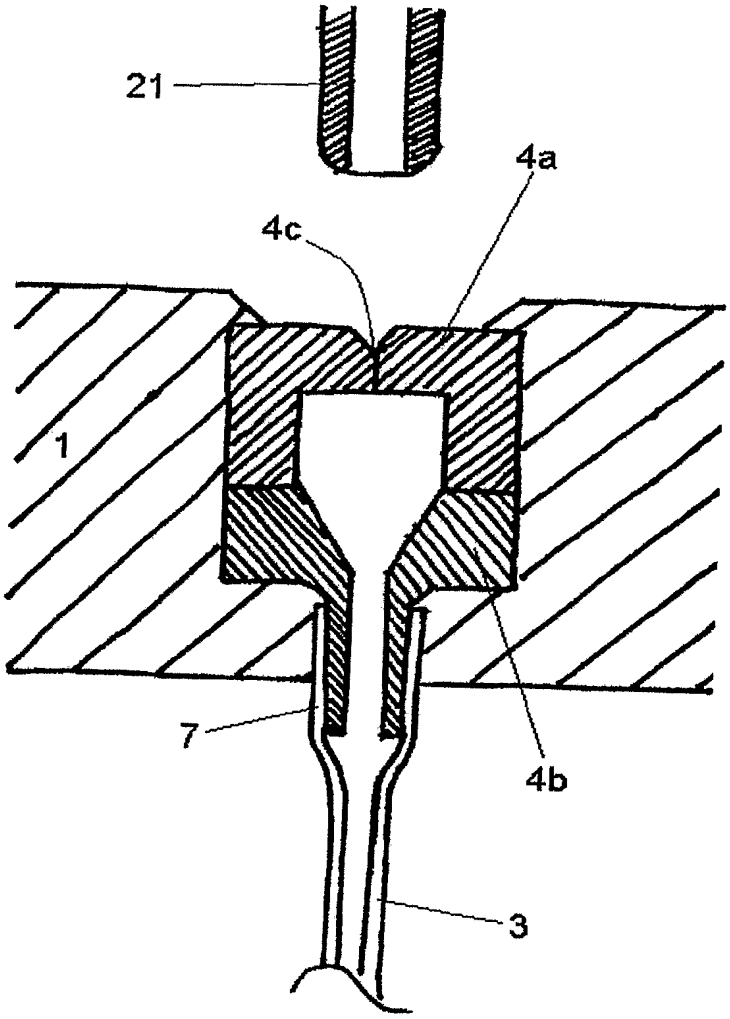


Fig. 15

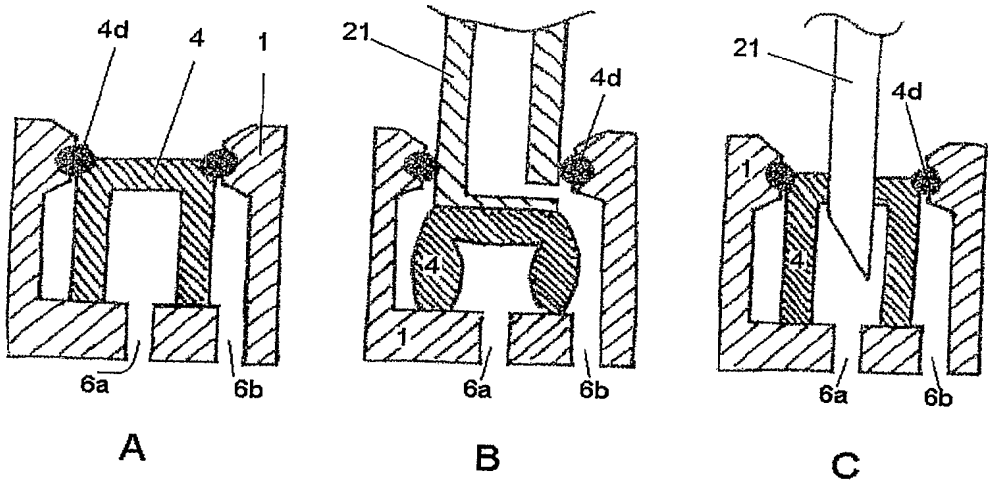


Fig. 16

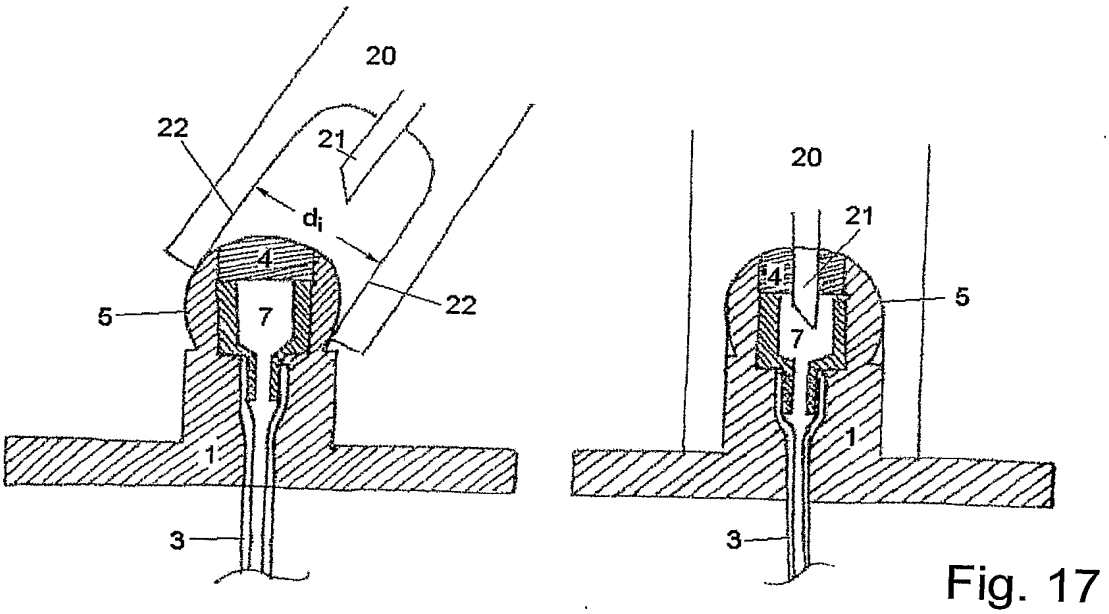


Fig. 17

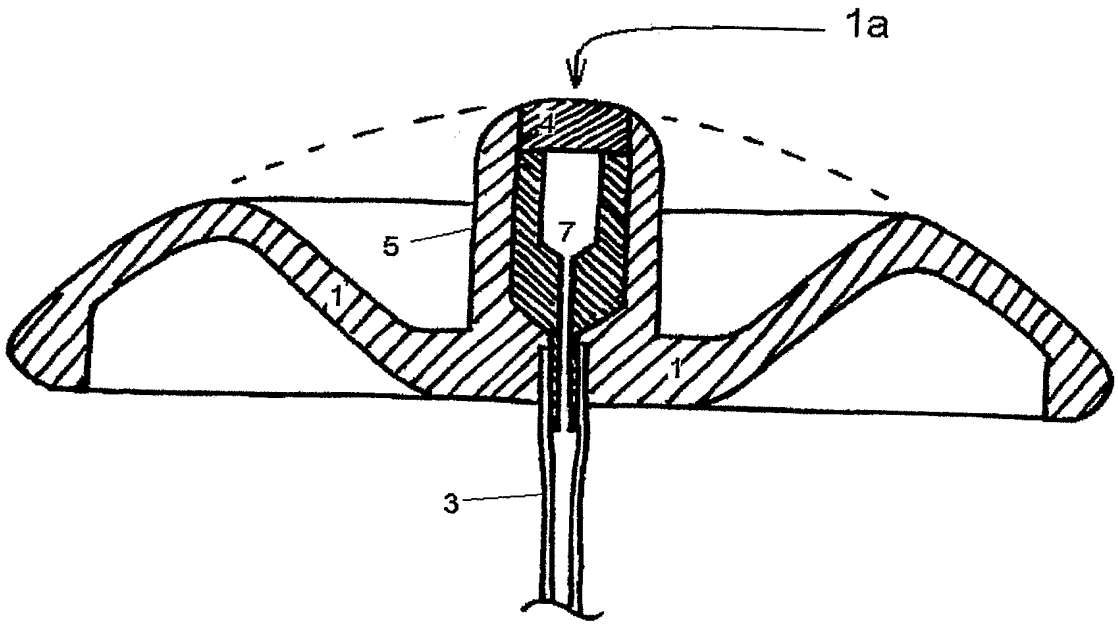


Fig. 18

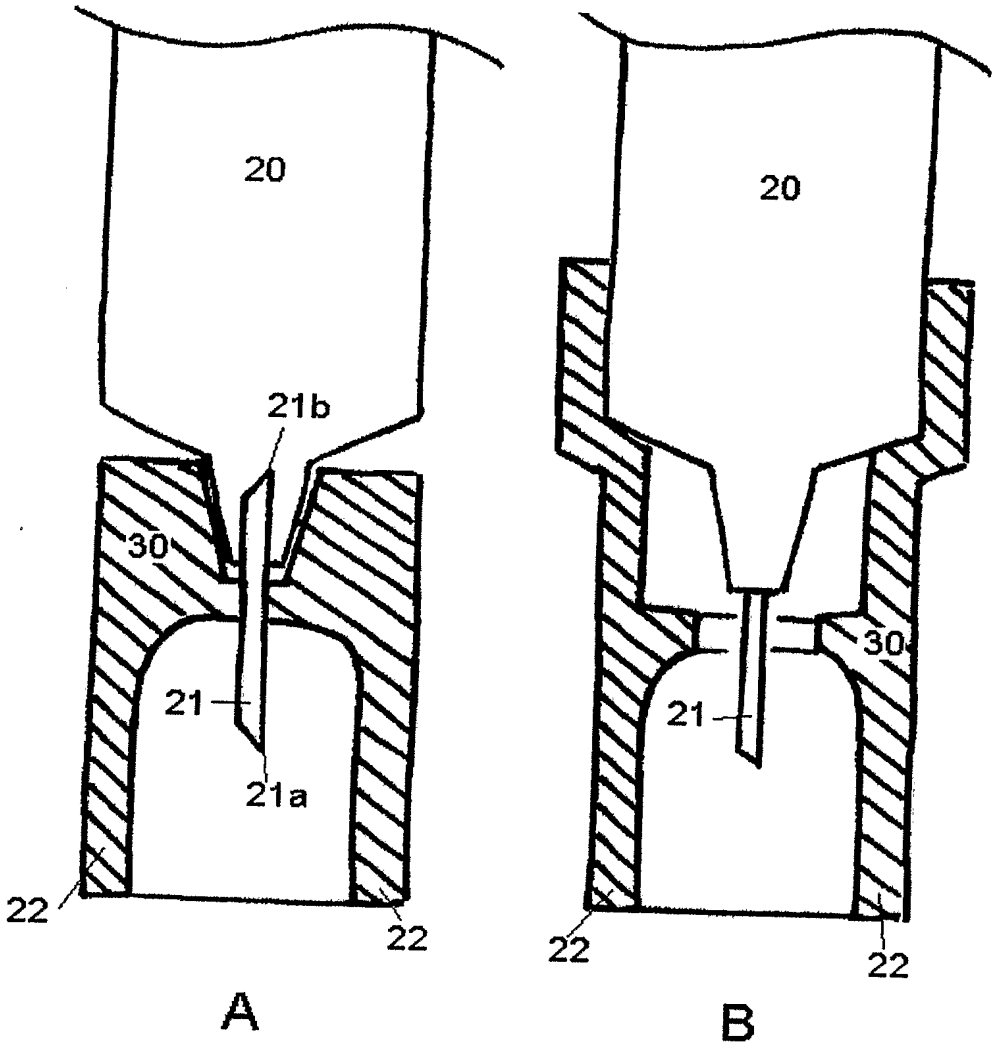


Fig. 19

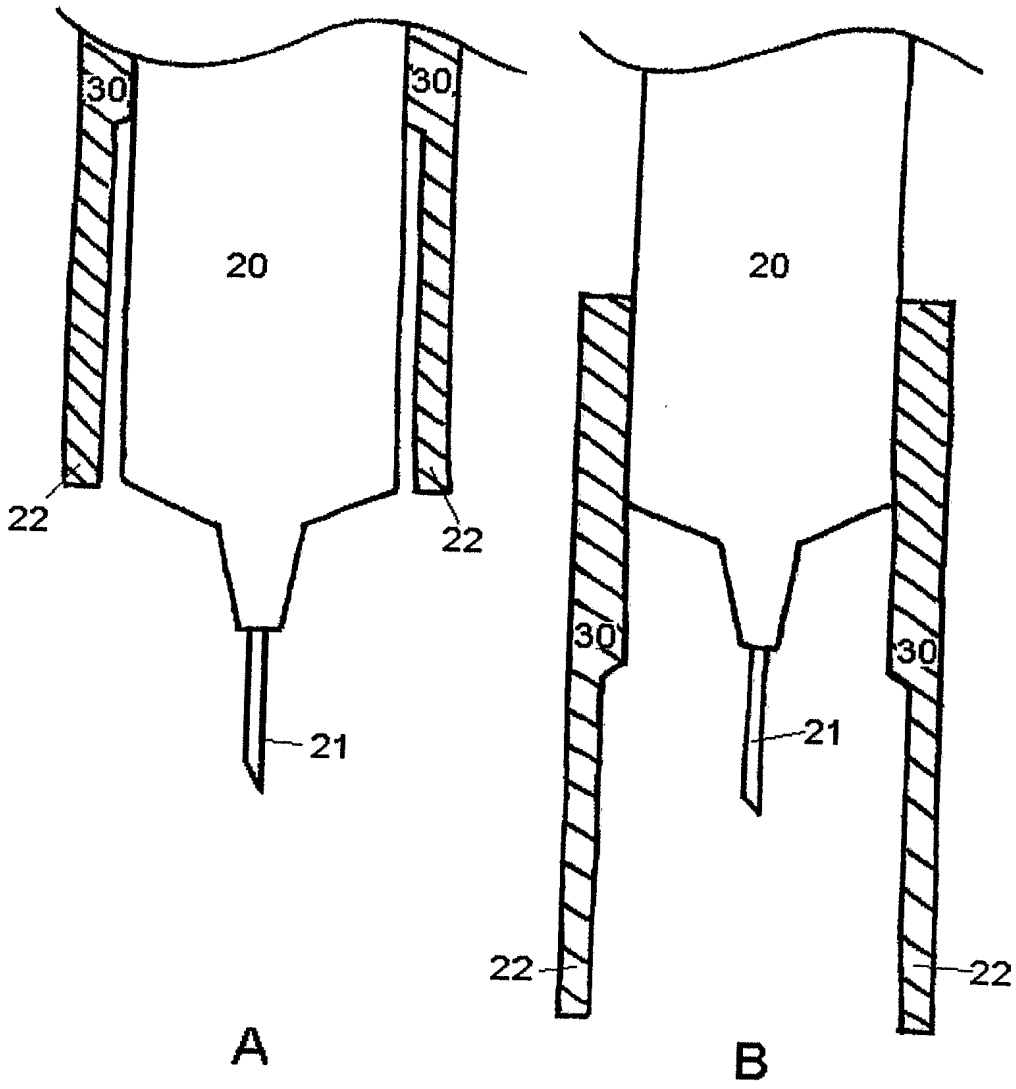


Fig. 20

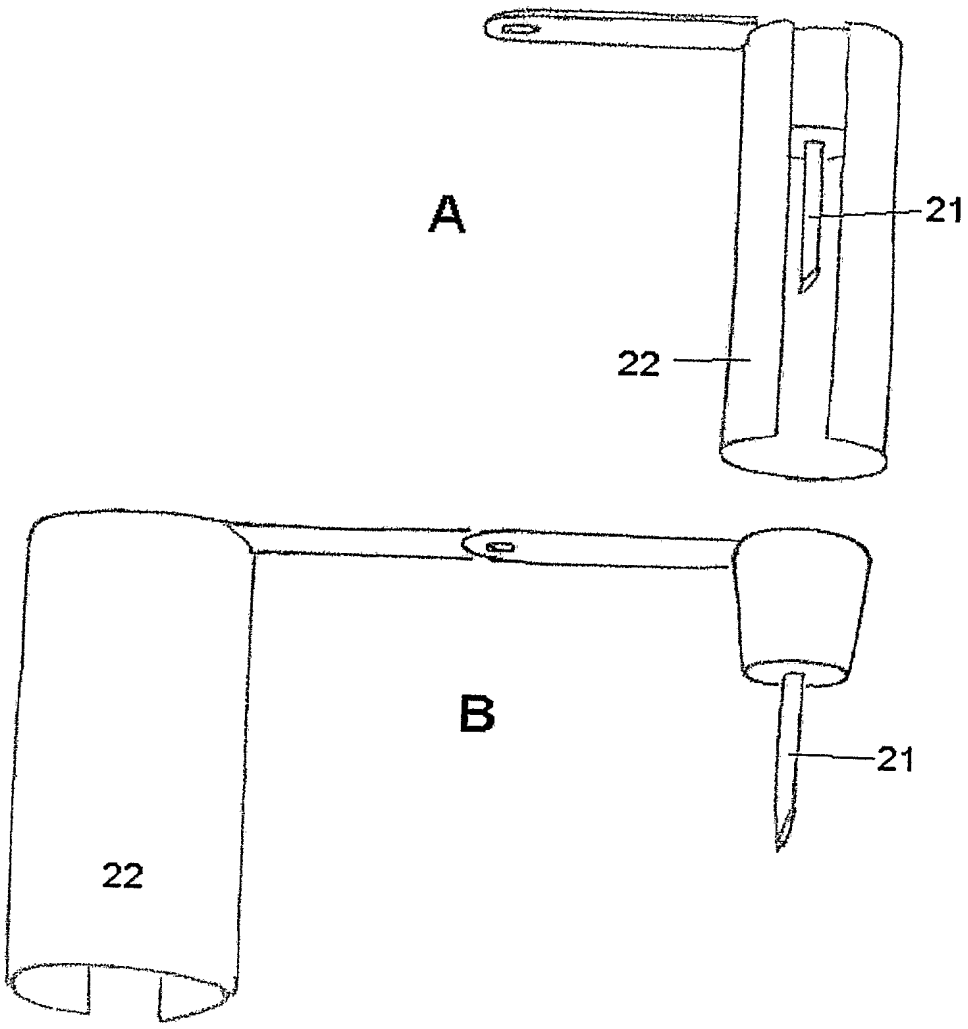


Fig. 21

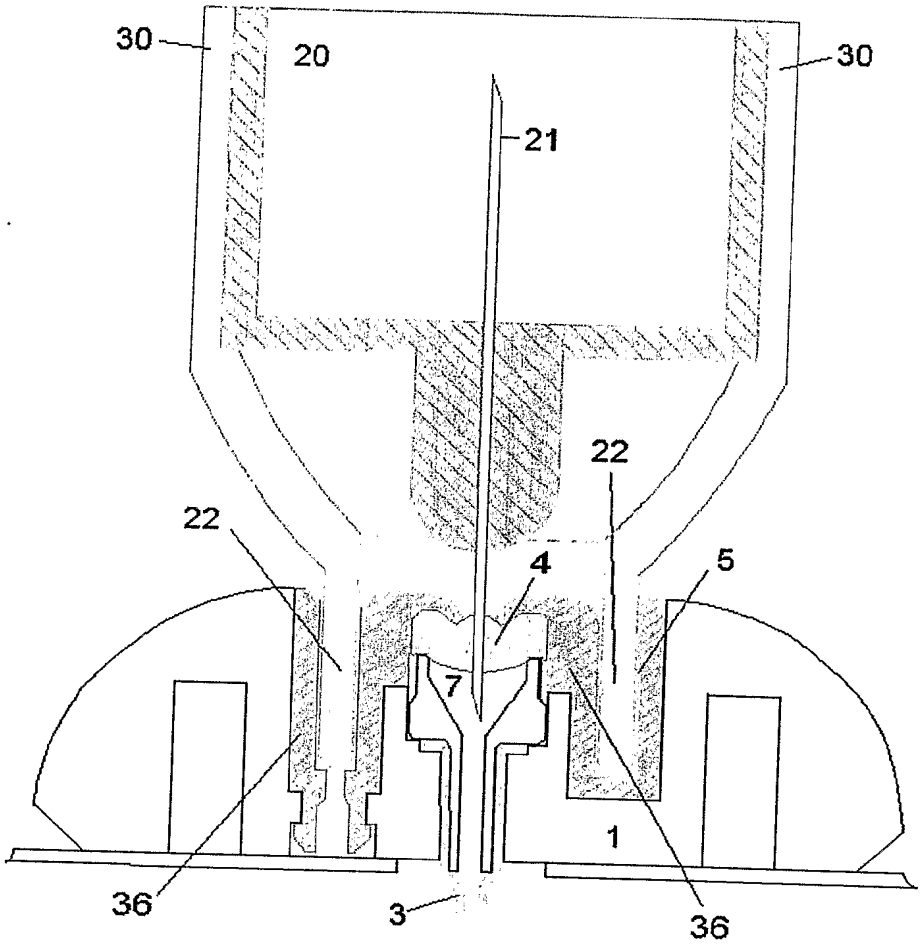


Fig. 22

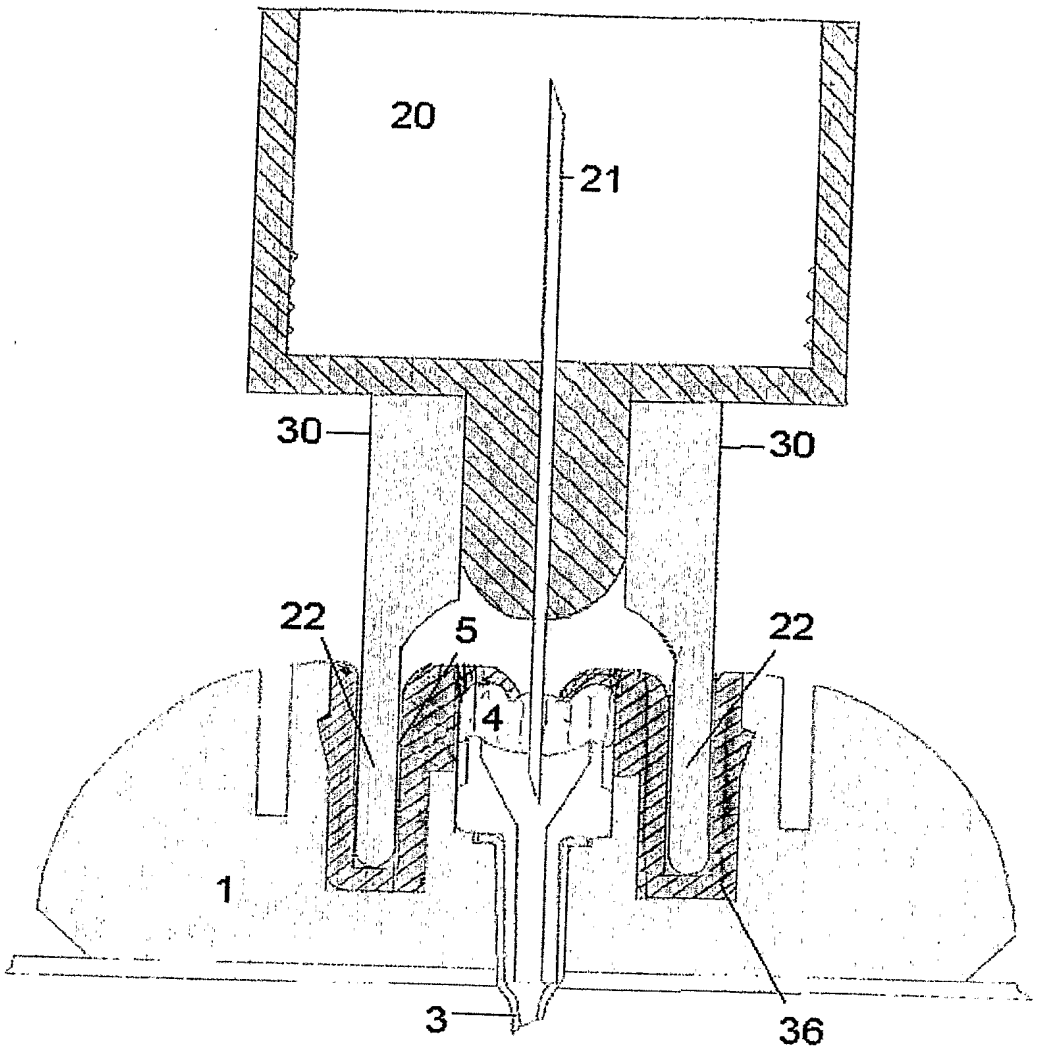


Fig. 23

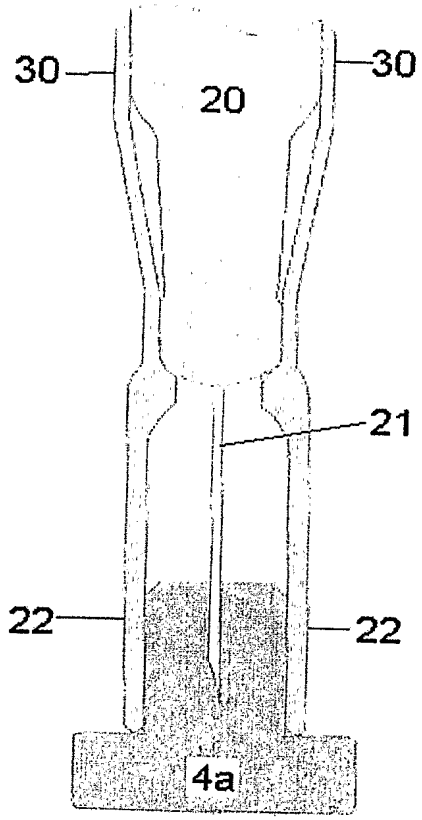


Fig. 24